IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

EDWARDS LIFESCIENCES AG and EDWARDS LIFESCIENCES, LLC,	)	C.A. No. 08-091-GMS
Plaintiffs,	)	
vs.	)	
COREVALVE, INC.,	)	
Defendant.	)	

DECLARATION OF JOHN DAVID EVERED IN SUPPORT OF COREVALVE, INC.'S MOTION TO TRANSFER VENUE PURSUANT TO 28 U.S.C. § 1404(a)

I, John David Evered, hereby declare as follows:

1. I am a partner in the law firm of Knobbe, Martens, Olson & Bear, LLP, counsel of record in this action for Defendant, CoreValve, Inc. I submit this declaration in support of CoreValve, Inc.'s Motion to transfer venue. I have personal knowledge of the following matters and, if called upon to testify, I would and could completely testify thereto.

2. Attached hereto as Exhibit 1 is a true and correct copy of the Complaint filed herein together with its exhibits, the patents-in-suit.

3. Attached hereto as Exhibit 2 are true and correct copies of General Order 98-03, and amending orders 01-01, and 02-06 of the U.S. District Court for the Central District of California.

4. Attached hereto as Exhibit 3 is a true and correct copy of the page entitled, "United States Locations" from Plaintiff Edwards LLC's website dated March 19, 2008.

5. Attached hereto as Exhibit 4 is a true and correct copy of the front page and extract from Plaintiff Edwards LLC's Form 10-K filed February 29, 2008.

6. Attached hereto as Exhibit 5 is a true and correct copy of United States Code Title

28 U.S.C. § 84(c).

7. Attached hereto as Exhibit 6 are true and correct copies of extracts from the Federal Court Management Statistics 2007 relating to the U.S. District Courts for the District of Delaware and the Central District of California.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Executed this 3rd day of April, 2008 at Irvine, California,

By: _____

John David Evered

CERTIFICATE OF SERVICE

I hereby certify that on April 4, 2008, I caused to be served by electronic service and hand delivery the foregoing document and electronically filed the same with the Clerk of Court using CM/ECF which will send notification of such filing(s) to the following:

Jack B. Blumenfeld
Morris, Nichols, Arsht & Tunnell, LLP
1201 North Market Street
P.O. Box 1347
Wilmington, DE 19899

I hereby certify that on April 4, 2008, the foregoing document was sent via Federal Express to the following non-registered participants:

John E. Nathan
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EXHIBIT 1

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

EDWARDS LIFESCIENCES AG and EDWARDS LIFESCIENCES LLC,	)	
Plaintiffs,	)	C.A. No. _____
v.	)	DEMAND FOR JURY TRIAL
COREVALVE, INC.,	)	
Defendant.	)	

COMPLAINT

Plaintiffs Edwards Lifesciences AG ("Edwards AG") and Edwards Lifesciences LLC ("Edwards LLC") (collectively, "Plaintiffs"), for their Complaint against Defendant CoreValve, Inc. ("CoreValve"), allege as follows:

JURISDICTION AND VENUE

1. This action arises under the Patent Laws of the United States, 35 U.S.C. § 1 et seq. This Court has jurisdiction over the subject matter of this action based on 28 U.S.C. §§ 1338(a) and 1331. Venue is proper under 28 U.S.C. §§ 1391(b) and (c) and 1400(b), because CoreValve resides in this Judicial District.

THE PARTIES

2. Plaintiff Edwards AG is a corporation organized and existing under the laws of Switzerland and having its principal executive offices in St.-Prex, Switzerland.

3. Plaintiff Edwards LLC is a limited liability company organized and existing under the laws of the State of Delaware and having its principal executive offices in Irvine, California.

4. Edwards AG is the assignee of the following United States Patents covering pioneering percutaneous heart valve products and methods of their use: U.S. Patent

No. 5,411,552, U.S. Patent No. 6,168,614, and U.S. Patent No. 6,582,462 (collectively, "Patents"). The Patents disclose and claim, *inter alia*, collapsible and expandable tissue valve prostheses and methods for replacing human heart valves using minimally invasive catheterization procedures.

5. Edwards LLC is the exclusive licensee of the Patents for the field of all cardiovascular applications.

6. Upon information and belief, Defendant CoreValve is a corporation organized and existing under the laws of the State of Delaware and having its principal place of business in Irvine, California.

7. Upon information and belief, CoreValve manufactures in the United States heart valve prostheses known as the "ReValving" system that infringe the Patents.

8. Upon information and belief, CoreValve has obtained European CE mark approval for its ReValving heart valve prostheses, and is currently offering its ReValving system for commercial sale in Europe.

FIRST CAUSE OF ACTION
(For Infringement of the '552 Patent)

9. Plaintiffs repeat and reallege the allegations of paragraphs 1 through 8 above.

10. On May 2, 1995, U.S. Patent No. 5,411,552 ("'552 Patent") (Exh. 1 hereto), entitled "Valve Prothesis for Implantation in the Body and a Catheter for Implanting such Valve Prothesis," was duly and legally issued to Drs. Henning Rud Andersen, John Michael Hasenkam, and Lars Lyhne Knudsen. Edwards AG is the assignee, and Edwards LLC is the exclusive licensee of the '552 Patent for the field of all cardiovascular applications. Plaintiffs are

the owners of all rights, title and interest in and to the '552 Patent, including all rights to recover for any and all past infringement thereof, in the field of all cardiovascular applications.

11. Upon information and belief, and in violation of 35 U.S.C. § 271, CoreValve has been and is now infringing the '552 Patent by manufacturing, using, importing, selling, offering to sell and/or supplying heart valve prostheses covered by one or more claims of the '552 Patent, including without limitation products designated as the ReValving system.

12. CoreValve's foregoing infringement has been willful and deliberate, rendering this case exceptional within the meaning of 35 U.S.C. § 285.

13. Plaintiffs have been damaged and will be irreparably injured by CoreValve's continuing infringement, for which Plaintiffs have no adequate remedy at law. CoreValve's infringing activities will continue unless enjoined by this Court.

SECOND CAUSE OF ACTION
(For Infringement of the '614 Patent)

14. Plaintiffs repeat and reallege the allegations of paragraphs 1 through 13 above.

15. On January 2, 2001, U.S. Patent No. 6,168,614 ("'614 Patent") (Exh. 2 hereto), entitled "Valve Prosthesis for Implantation in the Body," was duly and legally issued to Drs. Henning Rud Andersen, John Michael Hasenkam, and Lars Lyhne Knudsen. Edwards AG is the assignee, and Edwards LLC is the exclusive licensee of the '614 Patent for the field of all cardiovascular applications. Plaintiffs are the owners of all rights, title and interest in and to the '614 Patent, including all rights to recover for any and all past infringement thereof, in the field of all cardiovascular applications.

16. Upon information and belief, and in violation of 35 U.S.C. § 271, CoreValve has been and is now infringing the '614 Patent by supplying or causing to be supplied

in or from the United States a component of the invention claimed in the '614 Patent, including without limitation supplying the ReValving system, that is especially made or especially adapted for use in the invention and not a staple article or commodity of commerce suitable for substantial noninfringing use, knowing that such component is so made or adapted and intending that such component will be combined outside of the United States in a manner that would infringe the '614 Patent if such combination occurred in the United States.

17. CoreValve's foregoing infringement has been willful and deliberate, rendering this case exceptional within the meaning of 35 U.S.C. § 285.

18. Plaintiffs have been damaged and will be irreparably injured by CoreValve's continuing infringement, for which Plaintiffs have no adequate remedy at law. CoreValve's infringing activities will continue unless enjoined by this Court.

THIRD CAUSE OF ACTION
(For Infringement of the '462 Patent)

19. Plaintiffs repeat and reallege the allegations of paragraphs 1 through 18 above.

20. On June 24, 2003, U.S. Patent No. 6,582,462 ("'462 Patent") (Exh. 3 hereto), entitled "Valve Prosthesis for Implantation in the Body and a Catheter for Implanting such Valve Prosthesis," was duly and legally issued to Drs. Henning Rud Andersen, John Michael Hasenkam, and Lars Lyhne Knudsen. Edwards AG is the assignee, and Edwards LLC is the exclusive sublicensee of the '462 Patent for the field of all cardiovascular applications. Plaintiffs are the owners of all rights, title and interest in and to the '462 Patent, including all rights to recover for any and all past infringement thereof, in the field of all cardiovascular applications.

21. Upon information and belief, and in violation of 35 U.S.C. § 271, CoreValve has been and is now infringing the '462 Patent by manufacturing, using, importing, selling, offering to sell and/or supplying heart valve prostheses covered by one or more claims of the '462 Patent, including without limitation products designated as the ReValving system.

22. CoreValve's foregoing infringement has been willful and deliberate, rendering this case exceptional within the meaning of 35 U.S.C. § 285.

23. Plaintiffs have been damaged and will be irreparably injured by CoreValve's continuing infringement, for which Plaintiffs have no adequate remedy at law. CoreValve's infringing activities will continue unless enjoined by this Court.

PRAYER FOR RELIEF

WHEREFORE Plaintiffs demand judgment as follows:

(a) Finding that CoreValve has infringed the '552 Patent, the '614 Patent and the '462 Patent;

(b) Finding that CoreValve's infringement has been willful and deliberate;

(c) Preliminarily and permanently enjoining and restraining CoreValve, its officers, agents, servants, employees and attorneys, all parent, subsidiary and affiliate corporations and other related business entities, and all other persons or entities acting in concert, participation or in privity with one or more of them, and their successors and assigns, from infringing, contributing to the infringement of, or inducing others to infringe the '552 Patent, the '614 Patent and the '462 Patent;

(d) Awarding Plaintiffs damages, in an amount to be determined at trial, together with interest and costs as fixed by the Court;

(e) Awarding Plaintiffs enhanced damages under 35 U.S.C. § 284;

(f) Awarding Plaintiffs their reasonable attorneys' fees and their costs and disbursements in this action, as provided by 35 U.S.C. § 285; and

(g) Granting Plaintiffs such other and further relief as the Court deems just and proper.

JURY DEMAND

Plaintiffs demand a trial by jury on all issues so triable in this Complaint.

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February 12, 2008

EXHIBIT 1

US005411552A

United States Patent [19]

Andersen et al.

[11] Patent Number: 5,411,552

[45] Date of Patent: May 2, 1995

[54] **VALVE PROTHESIS FOR IMPLANTATION IN THE BODY AND A CATHETER FOR IMPLANTING SUCH VALVE PROTHESIS**

[76] Inventors: **Henning R. Andersen**, Dalvangen 37A, DK-8270 Hoejbjerg; **John M. Hasenkam**, Aprilvej 8, DK-8210 Aarhus V; **Lars L. Knudsen**, RudolfWulffsgade 6,4.mf., DK-8000 Aarhus C, all of Denmark

[21] Appl. No.: **261,235**

[22] Filed: **Jun. 14, 1994**

Related U.S. Application Data

[63] Continuation of Ser. No. 961,891, Jan. 11, 1993, abandoned.

[30] **Foreign Application Priority Data**

May 18, 1990 [DK] Denmark 1246/90

[51] **Int. Cl.**[6] **A61F 2/24**

[52] **U.S. Cl.** **623/2**; 623/900; 137/343; 137/844; 251/358

[58] **Field of Search** 623/2, 900; 137/343, 137/844, 316; 251/358; 606/108

[56] **References Cited**

U.S. PATENT DOCUMENTS

3,671,979	6/1972	Moulopoulos .	
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4,056,854	11/1977	Boretos et al.	623/2
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4,343,048	8/1982	Ross .	
4,733,665	3/1988	Palmaz	606/108
4,856,516	8/1989	Hillstead	604/194
5,037,434	8/1991	Lane	623/2
5,163,953	11/1992	Vince	623/2

FOREIGN PATENT DOCUMENTS

0357003	3/1990	European Pat. Off.	623/900
1271508	11/1986	U.S.S.R.	623/2
1371701	2/1988	U.S.S.R.	623/2

OTHER PUBLICATIONS

Derwent Abstract No. 87-190867/27 (1987), SU 1271508 (Gorkii Kirov Medical Ins.).

Primary Examiner—David H. Willse
Attorney, Agent, or Firm—Watson, Cole, Grindle & Watson

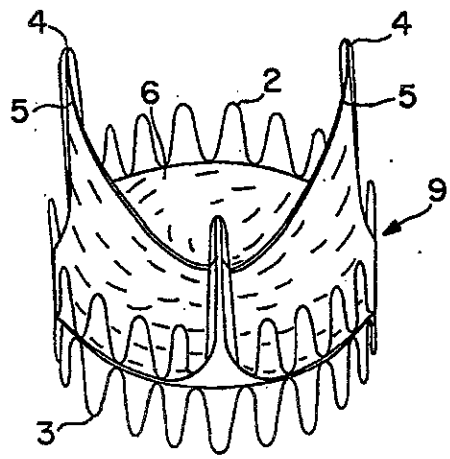
[57] **ABSTRACT**

A valve prosthesis (9) for implantation in the body by use of catheter (11) comprises a stent made from an expandable cylinder-shaped thread structure (2,3) comprising several spaced apices (4). The elastically collapsible valve (4) is mounted on the stent as the commissural points (5) of the valve (6) are secured to the projecting apices (4).

The valve prosthesis (9) can be compressed around the balloon means (13) of the balloon catheter (11) and be inserted in a channel, for instance in the aorta (10). When the valve prosthesis is placed correctly the balloon means (13) is inflated thereby expanding the stent and wedging it against the wall of aorta. The balloon means is provided with beads (14) to ensure a steady fastening of the valve prosthesis on the balloon means during insertion and expansion.

The valve prosthesis (9) and the balloon catheter (11) make it possible to insert a cardiac valve prosthesis without a surgical operation comprising opening the thoracic cavity.

8 Claims, 4 Drawing Sheets



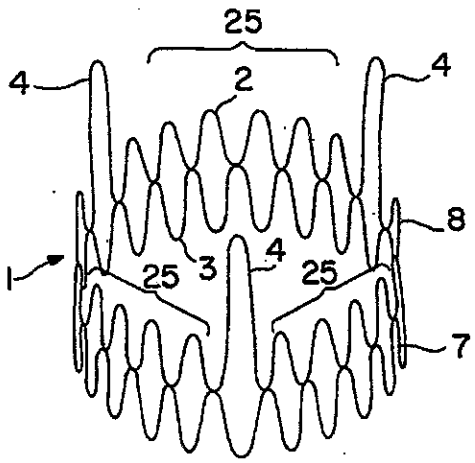


FIG. 1

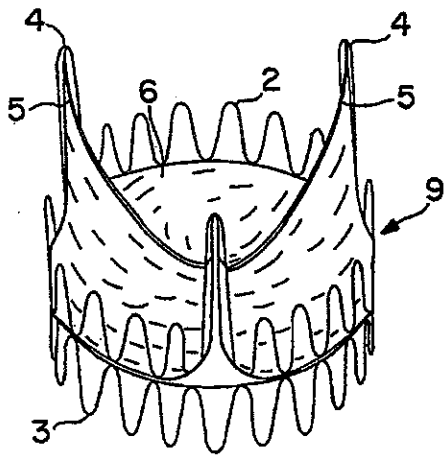


FIG. 2

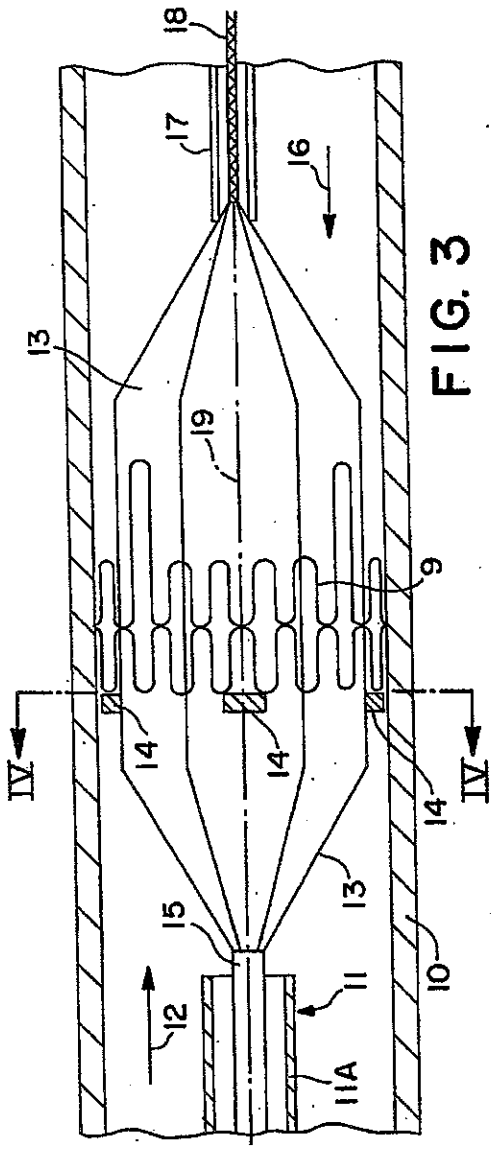


FIG. 3

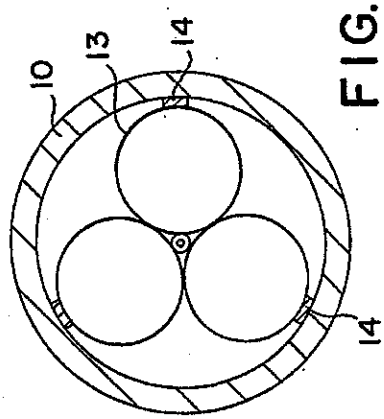


FIG. 4

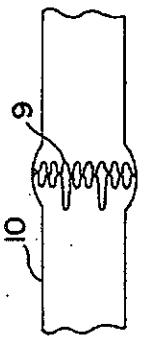


FIG. 7

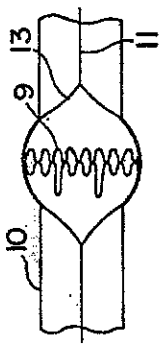


FIG. 6

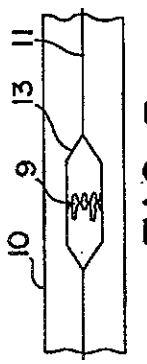


FIG. 5

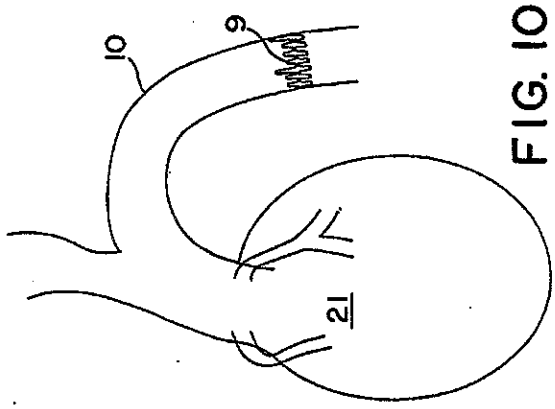


FIG. 10

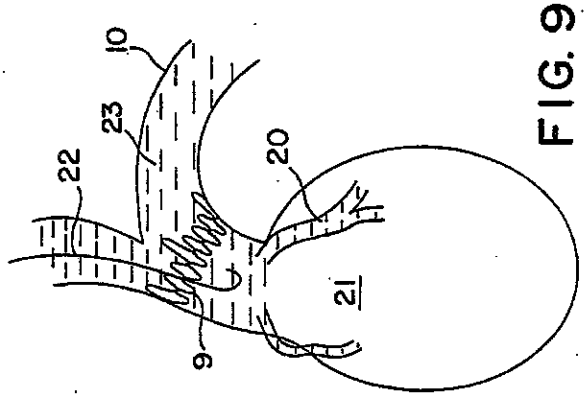


FIG. 9

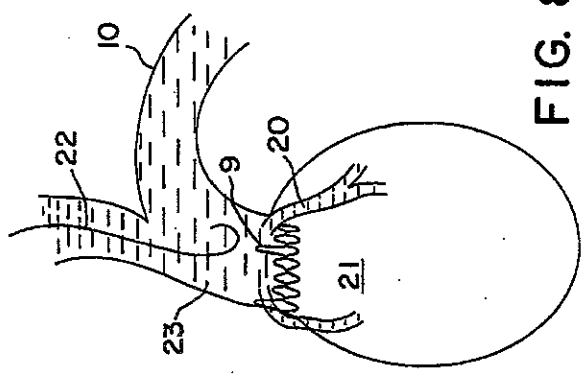


FIG. 8

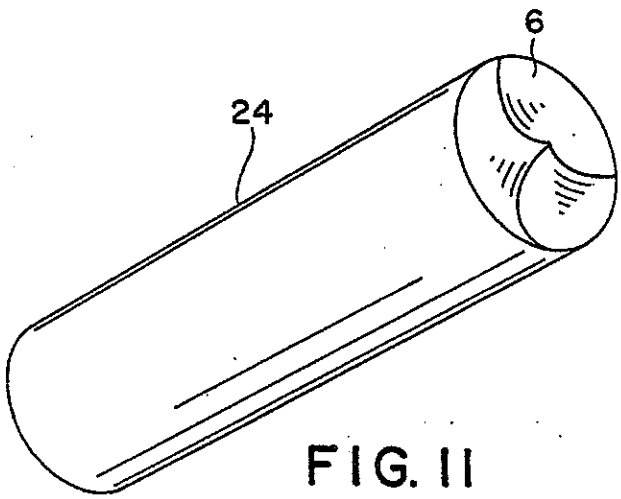


FIG. 11

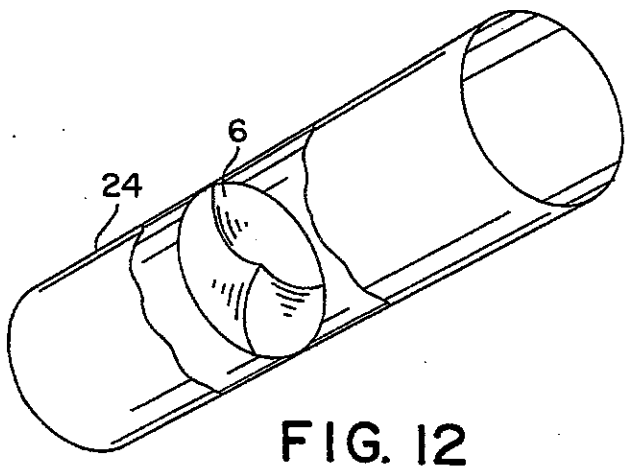


FIG. 12

VALVE PROTHESIS FOR IMPLANTATION IN THE BODY AND A CATHETER FOR IMPLANTING SUCH VALVE PROTHESIS

CROSS REFERENCE TO RELATED APPLICATION

This application is a continuation of application Ser. No. 961,891, filed Jan. 11, 1993, now abandoned.

BACKGROUND OF THE INVENTION

The present invention relates to a valve prosthesis, preferably a cardiac valve prosthesis, for implantation in the body and comprising a collapsible elastical valve which is mounted on an elastical stent wherein the commissural points of the elastical collapsible valve are mounted on the cylinder surface of the elastical stent.

Valve prostheses of this type are usually implanted in one of the channels of the body to replace a natural valve. In the present description the invention will be explained in connection with an cardiac valve prosthesis for implantation in aorta. However, it will be possible to use a valve prosthesis according to the invention in connection with implantation in other channels in the body by using the same technique as the one used for implantation of cardiac valve prosthesis. Such an implantation may, e.g., comprise the implantation of:

1. a valve (for instance a cardiac valve) in the veins,
2. a valve in the oesophagus and at the stomach,
3. a valve in the ureter and/or the vesica,
4. a valve in the biliary passages,
5. a valve in the lymphatic system, and
6. a valve in the intestines.

An existing natural valve in the body is traditionally replaced with a valve prosthesis by a surgical implantation. However, a surgical implantation is often an exacting operation. Thus, today the implantation of cardiac valves are solely made by surgical technique where the thoracic cavity is opened. The operation calls for the use of a heart and lung machine for external circulation of the blood as the heart is stopped and opened during the surgical intervention and the artificial cardiac valves are subsequently sewed in.

Due to its exacting character, it is impossible to offer such operation to certain people. For instance, this is due to the fact that the person is physically weak because of age or illness. Moreover, the number of heart and lung machines available at a hospital will be a substantially limiting factor.

Cardiac valve prostheses that need no surgical intervention are known as there are used for implantation by means of a technique of catheterization. Examples of such valve prostheses are described in U.S. Pat. Nos. 3,671,979 and 4,056,854. However, both of these valve prostheses are connected to means which lead to the surface of the patient either for a subsequent activation of the valve or for a subsequent reposition or removal of the valve prosthesis. With these valve prostheses it is impossible to make an implantation which makes it possible for the patient to resume a substantially normal life in the same way as it is possible in connection with a surgical implantation of a cardiac valve.

From U.S. Pat. No. 3,755,823 an elastic stent for a cardiac valve prosthesis is known. However, this valve prosthesis is not designed for implantation in the body by catheterization. Even though this patent contains no detailed explanation, the description indicates that this valve prosthesis is designed for implantation and sewering on by a surgical intervention.

Moreover, from U.S. Pat. Nos. 4,856,516 and 4,733,665 different shapes of expandable stents are known. These stents are made to be expanded by impression of a radially outward force coming from a balloon catheter or the like. These stents are made to reinforce the wall when there is a risk that the channel is closed and/or compressed.

The nearest prior art may be that described in GB-A-2,056,023. This document discloses an elastic stent as described by way of introduction. Thus, the stent described comprises an elastic collapsible valve mounted on the cylinder surface of a cylindrical stent. However, the valve prosthesis including the stent is designated for mounting through a surgical intervention. Even though the stent is slightly collapsible, it will not be suited for implantation by a catheterization procedure.

SUMMARY OF THE INVENTION

It is the object of the present invention to provide a valve prosthesis of the type mentioned in the introductory part, which permits implantation without surgical intervention in the body and by using a catheter technique known per se and which makes it possible for the patient to resume a substantially normal life.

This is achieved according to the invention with a valve prosthesis of the type mentioned in the introductory part, which is characterized in that the stent is made from a radially collapsible and re-expandable cylindrical support means for folding and expanding together with the collapsible valve for implantation in the body by means of a technique of catheterization.

The collapsible elastic valve is mounted on the stent for instance by gluing, welding or by means of a number of suitable sutures.

If the support means are made from a thread structure, this can for instance be grate shaped, loop shaped or helical. This makes it possible to compress the stent and the collapsible valve mounted thereon for placing on the insertion catheter. The use of a non-self-expandable stent may, e.g., be effected by a compression of the stent around the expansion arrangement of the catheter which preferably consists of a balloon. When using a self-expandable stent, a catheter with an expansion arrangement is not used. In this case the stent is compressed and is inserted into an insertion or protection cap from which the stent is eliminated after implantation in order to obtain an expansion due to the stresses in the compressed support means, which for instance may be made from plastics or metal. After the compression the entire outer dimension is relatively small, which makes it possible to introduce the valve prosthesis through a channel in the body.

When the valve prosthesis is introduced and placed correctly, the stent is expanded by self-expansion or by means of the expansion arrangement until the stent is given an outer dimension which is slightly larger than the channel in which it is placed. As the stent is elastic, a contraction of the stent is prevented once it is expanded. The stiffness in the material of the support means contributes to maintain the expanded shape of the stent. After the expansion is made, the expansion arrangement of the catheter is contracted and the catheter can be removed from the channel. The inlet opening can subsequently be closed and the patient will then be able to resume a normal life.

The valve prosthesis according to the invention does not require an actual operation but merely a small intervention to optionally expose the body channel, e.g., a vein, through which the insertion takes place. Thus, patients for whom an operation would be associated with high risk can be offered implantation of, for instance, cardiac valves. After the implantation has taken place, the after-treatment will advantageously be shorter than normally, which means fewer hospital days for the patient. Moreover, it is assumed that it will be possible to implantate the valve prosthesis under local anaesthetic.

The valve prosthesis can be used to replace a natural valve or to establish a new valve function in one of the channels in the body which do not naturally contain a valve. For instance this goes for veins (arteries and veins) on a place without natural valves. The function of the valve prosthesis is then to ensure that the blood flows in one direction only. The valve is meant to be used in veins in the legs of persons suffering from varicose veins (varices).

In persons having varicose veins the blood flows in a wrong direction, viz. from the central veins in the centre of the leg towards the superficial veins. Among other things, this is due to the changed pressure in the legs, upright working position and other conditions. A valve prosthesis according to the invention may easily be placed in the veins and prevent the flow of the blood in a wrong direction.

Also, the valve prosthesis can be used in connection with diseases, for instance cancerous tumors, where too much humour is produced. If the humour is able to flow from the cancerous tumor through several channels, it is possible to drain the humour in one desired direction through the channels of the body by an appropriate placing of the valve prosthesis.

When the valve prosthesis is used as a cardiac valve prosthesis in the aorta, it is possible to mount it in three positions, viz., in the descending part of the aorta, in a position between the coronary arteries and the left ventricle of the heart, or in the aorta in a position immediately after the mouth of the coronary arteries.

The cardiac valve prosthesis can also be used in other places than in the aorta. Thus, the valve prosthesis can be used in the pulmonary artery and/or the right ventricle of the heart for replacing the pulmonary valves. Likewise, the cardiac valve prosthesis can be used in the passage between the right auricle of the heart and the right ventricle of the heart (tricuspidalostium) and the passage between the left auricle of the heart and the left ventricle of the heart (mistralostium) for replacing the tricuspidal valve and the mitral valve, respectively.

Even though the cardiac valve preferably is meant to be used for patients suffering from aorta insufficiency and who cannot be offered an open heart surgery, the valve prosthesis can also be used for patients in connection with treatment of aorta stenosis. Several of the patients with aorta stenosis are elderly people who cannot be offered a surgical cardiac operation. The patients are offered balloon dilatation of the aorta stenosis which may result in an aorta insufficiency as a side effect of the treatment.

As to these patients it is possible to insert a valve prosthesis in the descending or ascending part of the aorta thoracalis a few days or weeks before the balloon dilatation. As a result thereof, the left ventricle is protected against weight if the subsequent balloon dilatation of the stenosis results in aorta insufficiency. In certain cases the weight (reflux) on the left ventricle is reduced by up to approximately 75%.

Furthermore, the stent may be made with a relatively great height and with a cylinder surface which is closed by a suitable material. Thus, a vascular prosthesis known per se is formed wherein the valve is mounted. This may facilitate the implantation of the valve prosthesis, for instance in the arcus aorta. Moreover, the great surface which abuts the inner wall of the channel contributes to ensure the securing of the valve prosthesis in the channel. This embodiment is also suitable as valve prothesis which is inserted in veins. As veins have relatively thin and weaker walls than arteries, it is desirable that the valve prothesis has a greater surface to distribute the outward pressure which is necessary to secure the valve prosthesis.

Moreover, the invention relates to a balloon catheter for implantating a valve prosthesis according to the invention and comprising a channel for injection of a fluid for the inflation of the balloon means of the catheter and an insertion cap wherein the balloon means of the catheter and a collapsible valve prosthesis mounted thereon are located during the injection, characterized in that the balloon means are provided with a profiled surface which is made to ensure a steady fastening of the valve prosthesis during the withdrawal of the balloon means from the protection cap and the subsequent inflation for the expansion of the stent.

Different balloon catheters for implantating cores in the body are known. For instance, such balloon catheters are known from U.S. Pat. Nos. 4,856,516, 4,733,665 and 4,796,629 and from DE publication No. 2,246,526. However, the known balloon catheters have a smooth or a slightly wavy surface. The use of such balloon catheter is disadvantageous for mounting a valve prosthesis in a channel having a large flow as for instance the aorta. A large humour flow is able to displace the stent on the smooth surface of the balloon and makes an accurate positioning difficult. This drawback has been remedied with the balloon catheter according to the present invention as the profiled surface prevents a displacement of the valve prosthesis in relation to the balloon means during introduction and the subsequent inflation of the balloon means.

In connection with the implantation, any prior art technique may be used to supervise an accurate introduction and positioning of the valve prosthesis. Thus, guide wires for the catheter, X-ray supervision, injection of X-ray traceable liquids, ultrasonic measuring, etc., may be used.

DESCRIPTION OF THE DRAWINGS

The invention will now be explained in detail with reference to the accompanying schematical drawing, wherein

FIG. 1 shows a perspective view of a stent without a valve,

FIG. 2 is a perspective view of a valve prosthesis according to the invention made from the stent shown in FIG. 1 having a biological valve mounted thereon,

FIG. 3 is a partial view through the aorta illustrating a partially inflated balloon catheter,

FIG. 4 is a cross section through the embodiment shown in FIG. 9,

FIG. 5–7 are views illustrating the introduction and implantation of a valve prosthesis of the invention in the aorta,

FIG. 8–10 are views illustrating three possible positions of a cardiac valve prosthesis, and

FIG. 11–12 are perspective views illustrating two further embodiments of a valve prosthesis having a closed cylindrical wall.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

FIG. 1 shows a stent 1 made by support means in the form of two 0.55 mm surgical stainless steel wires 2,3. The wires are folded in 15 loops. Three loops 4 are 14 mm in height and are intended to secure the commissural points 5 (see FIG. 2) from a biological cardiac valve 6 which is mounted in the stent 1. The remaining loops have a height of 8 mm. These loops form circumferentially expandable sections 25 between the commissural points 5 forming commissural supports. Each of the two folded wires 2,3 is bent to form rings 7,8 which are closed by welding the ends. The two rings are placed on top of each other as will appear from FIG. 1 and they are mutually secured by means of a number of sutures (not shown). The lower ring is circumferentially expandable at least along sections thereof which correspond to the circumferentially expandable sections 25. By using a substantially cylindrical thread structure with projecting apices, a reduction in weight is obtained as compared to a stent which is exclusively cylindrical with the same loop heights for all the loops.

The biological valve 6 was removed from a slaughtered pig of 100 kg. The valve was cleaned before mounting in the stent 1. The cleaned valve has an outer diameter of 25–27 mm and the height of the three commissural points 5 is 8 mm. The valve 6 is mounted in the stent by means of a suitable number of sutures to form the cardiac valve prosthesis 9 shown in FIG. 2. The valve prosthesis produced is used for performing tests in pigs by implantation of cardiac valve prosthesis. However, the cardiac valve prosthesis for use in human beings has a corresponding form.

FIG. 3 shows a partial view through the aorta 10. A balloon catheter 11 is introduced in the aorta according to the direction of an arrow 12. In the Figure shown the balloon means 13 of the balloon catheter is led out of the protection cap 11A and is partly inflated through a fluid channel 15, which is led to the surface of the patient. The balloon means 13 constitutes a tri-sectional balloon upon which the cardiac valve prosthesis is placed. In the form shown, the cardiac valve prosthesis is expanded exactly to be in contact with the aorta 10. The balloon means 13 is provided with three projecting beads 14 which are engaged with the one side of the cardiac valve prosthesis 9. The blood flowing through the aorta according to the direction of an arrow 16 will thus cause the cardiac valve prosthesis 9 to abut on the beads 14 and the valve cannot be displaced in relation to the balloon means 13. Moreover, the balloon catheter used comprises a central channel 17 to receive a guide wire 18 which is used in a way known per se for supervising the introduction of the catheter through fluoroscopi. In the shown embodiment beads 14 are only used at one side of the valve prosthesis, but, however, it will often be desirable to use the beads in pairs placed along lines parallel to the longitudinal axes 19 through the balloon means 13. In this case the spacing of the pair of beads 14 will correspond to the height of the loops of the stent. This makes it possible to make an effective fastening of a valve prosthesis on balloon means. Moreover, the fastening on the balloon means may be provided by using balloon means with an indentation in the surface (not shown).

FIG. 4 shows a cross section through the embodiment shown in FIG. 3 illustrating the placing of the beads 14 on the tri-sectional balloon means 13.

A balloon catheter of the above-described type which was used in tests of implantating the cardiac valve prosthesis 9 in pigs had the following dimensions. Each of the three balloons was 60 mm in length and 15 mm in diameter. The total diameter for the three inflated balloons was 31 mm and in the balloon catheter used two beads 14 having a height of 3 mm were mounted on each side of the three balloons. The beads had a spacing of 15 mm. The protection cap 11A of the balloon catheter had an outer diameter of 13.6 mm and an inner diameter of 12.5 mm and a length of 75 cm. The balloon catheter was provided with a standard guide wire having a diameter of 0.9 mm and a length of 300 cm.

FIGS. 5–7 show the valve prosthesis 9 at different steps in introducing and implantating in the aorta 10 by means of the catheter 11 having the inflatable balloon means 13. The cardiac valve prosthesis 9 is initially placed above the deflated balloon means 13 and compressed manually around the balloon means (FIG. 5), whereafter the outer diameter for the valve prosthesis is approximately 10 mm. After the introduction and positioning, the balloon means 13 is inflated (FIG. 6), thereby contributing an outer dimension of approximately 30 mm to the cardiac valve prosthesis. To obtain an effective fastening in the aorta, the outer dimension of the cardiac valve prosthesis is greater than the diameter of the aorta. This means that the prosthesis is tight against the inner wall of the aorta with a pressure which is sufficiently large to counteract a detachment due to the flow of the blood. The balloon catheter 11 may subsequently be removed from the aorta 10 (FIG. 7). Due to the stiffness of the metal the valve prosthesis will prevent a contraction. However, smaller contractions may occur (<10% diameter reduction) after the deflation and removal of the balloon catheter 13. When the valve prosthesis is mounted as shown in FIG. 7, the patient will be able to resume a substantially normal life after a few days.

FIGS. 8–10 show the positioning of the valve prosthesis 9 as cardiac valve prosthesis in the aorta 10 in three different positions, i.e., in a position between the coronary arteries 20 and the left ventricle of the heart 21 (FIG. 8), in a position immediately after the mouth of the coronary arteries in the ascending part of the aorta (FIG. 9), and in a position in the descending part of the aorta 10. The positioning of the valve prosthesis is chosen in accordance with the diagnosis of the illness of the patient. By placing the cardiac valve prosthesis as shown in FIG. 8, there is a risk of detachment and/or covering the mouth of the coronary arteries, and therefore it is preferred to use a higher stent which, for instance, comprises several rings 7,8 placed on top of each other. This allows a fixation of the prosthesis at a place after the mouth of coronary arteries even though the valve itself is in the position between the coronary arteries and the left ventricle. FIGS. 8 and 9 show how a contrast medium 23 is injected by means of a so-called pigtail catheter for registration of the tightness of the implantated valve prosthesis 9.

A specific embodiment for a valve prosthesis and a balloon catheter for implantating the valve prosthesis has been explained above. However, it is obvious that it

is possible to modify the valve prosthesis depending on the desired use, and moreover, it is possible to modify the catheter used in the implantation. Thus, the stent of the valve prosthesis may be made solely of one closed ring folded in a number of loops or with three or more mutually secured loop-shaped rings placed on top of each other. Moreover, it is possible to make the stent having a thread structure which instead of loops is grate shaped, helical or is formed otherwise if only it is ensured that the form of the stent permits the compression and expansion of the stent and fastening of the collapsible valve. Instead of a biological valve it might be possible to use other collapsible valves, such as valves made from synthetic materials, e.g., polyurethane. It is also possible to use valves with more or fewer flaps than three.

It is possible to make the valve prosthesis with a closed cylinder surface as illustrated in FIGS. **11** and **12**. In both Figures the support means of the valve prosthesis is made of an elongated tubular means **24** having a closed cylinder surface. This valve prosthesis is intended to expand by self-expansion or by means of a catheter according to the invention. This prosthesis is especially suitable for placing in veins and other channels where only a small pressure is exerted against he wall of the channel. In FIG. **11** the valve **6** is mounted at the end of the tubular means **24**. In FIG. **12** an embodiment is shown where the valve **6** is mounted in a central position in the tubular means **24**.

An explanation of a method of implantating a valve prosthesis according to the invention is given below:

- a valve prosthesis **9** made of a stent **1** and a collapsible valve **6**, as described above, is placed on a deflated balloon means and is manually compressed thereon,
- the balloon means **13** and the valve prosthesis are drawn into an insertion cover **11A**,
- a guide wire **18** is inserted into the left ventricle of the heart through the central opening **17** of the balloon catheter under continuous fluoroscopi,
- the insertion cover **11A** conveys the guide wire **18** to a point in the channel in the immediate vicinity of the desired position of the valve prosthesis,
- the balloon means **13** is pushed out of the protection cap **11A** and the valve prosthesis is positioned in the desired position if necessary by use of further registration means to ensure an accurate positioning,
- the balloon means **13** is inflated with a certain overstretching of the channel,
- the balloon means **13** is deflatated, and
- the balloon means **13**, the guide wire **18** and the protection cap **11A** are drawn out and the opening in the channel, if any, wherein the valve prosthesis is inserted can be closed.

We claim:

1. A valve prosthesis for implantation in a body channel, the valve prosthesis comprising a collapsible elastical valve which is mounted on an elastical stent, the elastical valve having a plurality of commissural points, wherein the stent comprises:

cylindrical support means which is radially collapsible for introduction within the body channel and which has a plurality of circumferentially-expandable sections such that the cylindrical support means is radially expandable for being secured within the body channel; and

a plurality of commissural supports projecting from one side of the cylindrical support means in a direction generally parallel to the longitudinal axis thereof for supporting the commissural points of the collapsible valve, at least one circumferentially-expandable section of the cylindrical support means lying between each of the commissural supports, such that the collapsible valve may be collapsed and expanded together with the cylindrical support means for implantation in the body channel by means of a technique of catheterization.

2. A valve prosthesis according to claim **1**, wherein the cylindrical support means is made of a thread structure.

3. A valve prosthesis according to claim **2**, wherein the thread structure comprises several spaced apices projecting from the one side of the cylindrical structure and in a direction along the longitudinal axis of the cylinder and that the commissural points of the valve are attached to the projecting apices.

4. A valve prosthesis according to claim **3**, wherein the elastically collapsible valve is a biological trilobate valve.

5. A valve prosthesis to claim **4**, wherein the stent is made from a stainless steel wire folded in a number of loops and bent into a circle and welded to form a closed ring, wherein the stent comprises two or more such closed rings which are mutually connected end to end to form the cylindrical thread structure, and wherein three of the loops in a ring at an end of said stent are folded with a greater height than the remaining loops to form the apices to which the commissural points of the biological valve are attached.

6. A valve prosthesis according to claim **5**, wherein each of the rings of the stent is made from a wire having a diameter of 0.55 mm and a loop height of approximately 8 mm and approximately 14 mm for the three greater loops, and wherein the cylindrical thread structure produced and the collapsible valve mounted thereon in a folded state have an outer diameter of approximately 10 mm and in expanded state an outer diameter of approximately 30 mm.

7. A valve prosthesis according to claim **5**, wherein the stent is made to be fixed through the expansion at one point in the channel wherein the valve prosthesis is inserted, which point is different from the point where the valve is mounted in the stent.

8. A valve prosthesis according to claim **1**, wherein the cylinder surface of the support means is closed to form a tubular element.

* * * * *

EXHIBIT 2

US006168614B1

(12) **United States Patent**
Andersen et al.

(10) **Patent No.: US 6,168,614 B1**
(45) **Date of Patent: *Jan. 2, 2001**

(54) **VALVE PROSTHESIS FOR IMPLANTATION IN THE BODY**

(75) Inventors: **Henning Rud Andersen**, Hoejbjerg; **John Michael Hasenkam**; **Lars Lyhne Knudsen**, both of Aarhus, all of (DK)

(73) Assignee: **Heartport, Inc.**, Redwood City, CA (US)

(*) Notice: This patent issued on a continued prosecution application filed under 37 CFR 1.53(d), and is subject to the twenty year patent term provisions of 35 U.S.C. 154(a)(2).

Under 35 U.S.C. 154(b), the term of this patent shall be extended for 0 days.

This patent is subject to a terminal disclaimer.

(21) Appl. No.: **09/026,574**

(22) Filed: **Feb. 20, 1998**

Related U.S. Application Data

(62) Continuation of application No. 08/955,228, filed on Oct. 21, 1997, now abandoned, which is a division of application No. 08/801,036, filed on Feb. 19, 1997, now Pat. No. 5,840,081, which is a continuation of application No. 08/352,127, filed on Dec. 1, 1994, now abandoned, which is a division of application No. 08/261,235, filed as application No. PCT/DK91/00134 on May 16, 1991.

(30) **Foreign Application Priority Data**

May 18, 1990 (DK) 1246-90

(51) **Int. Cl.**[7] **A61F 2/06**

(52) **U.S. Cl.** **623/1**; 623/2; 623/12; 623/900

(58) **Field of Search** 623/1, 2, 12, 11, 623/900

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Primary Examiner—Jeffrey A. Smith
(74) *Attorney, Agent, or Firm*—Jens E. Hoekendijk; Michael J. Lynch

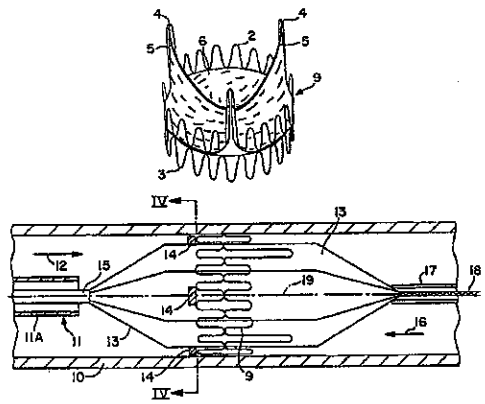
(57) **ABSTRACT**

A valve prosthesis (9) for implantation in the body by use of catheter (11) comprises a stent made from an expandable cylinder-shaped thread structure (2,3) comprising several spaced apices (4). The elastically collapsible valve (6) is mounted on the stent as the commissural points (5) of the valve (6) is secured to the projecting apices (4).

The valve prosthesis (9) can be compressed around the balloon means (13) of the balloon catheter (11) and be inserted in a channel, for instance in the aorta (10). When the valve prosthesis is placed correctly the balloon means (13) is inflated thereby expanding the stent and wedging it against the wall of the aorta. The balloon means is provided with beads (14) to ensure a steady fastening of the valve prosthesis on the balloon means during insertion and expansion.

The valve prosthesis (9) and the balloon catheter (11) make it possible to insert a cardiac valve prosthesis without a surgical operation comprising opening the thoracic cavity.

25 Claims, 4 Drawing Sheets



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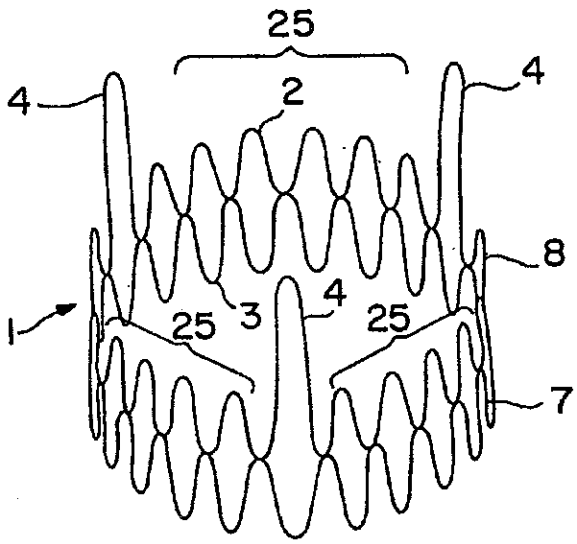

FIG. 1

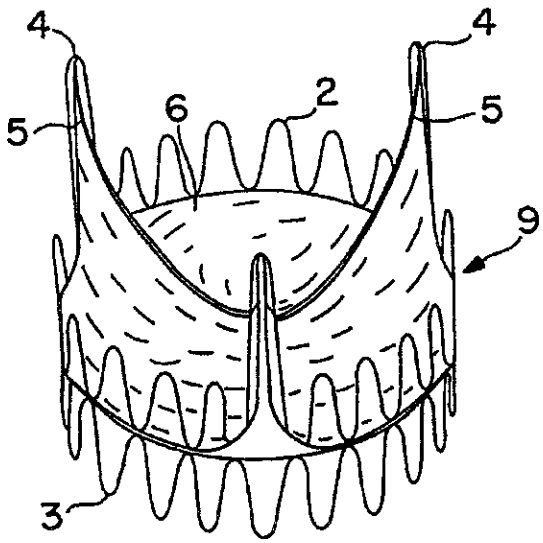

FIG. 2

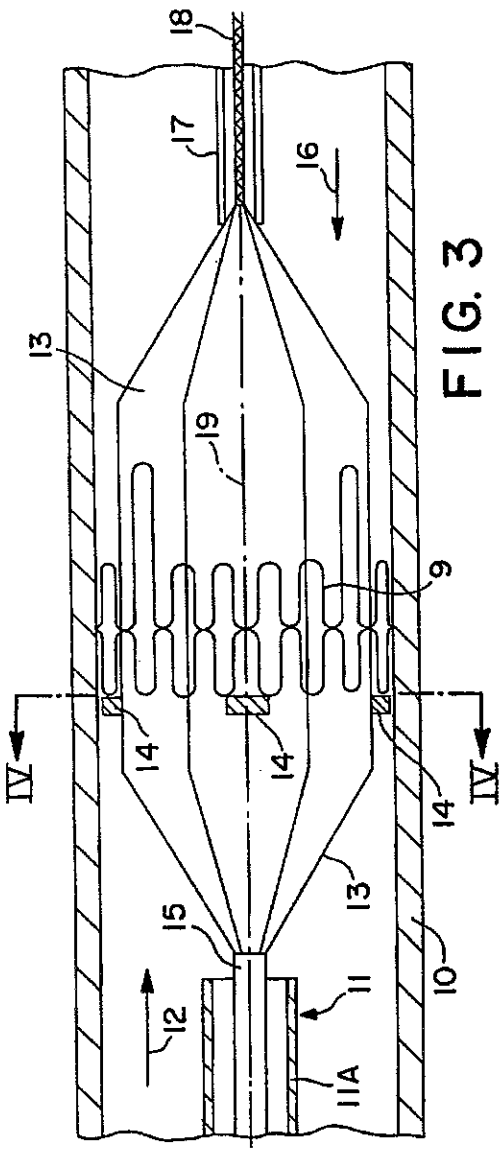

FIG. 3

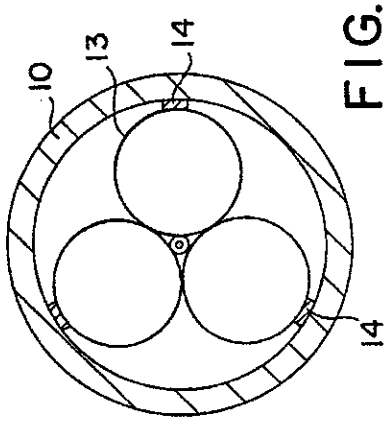

FIG. 4

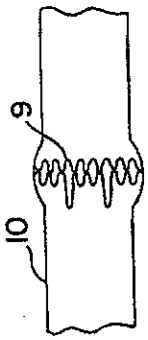

FIG. 7

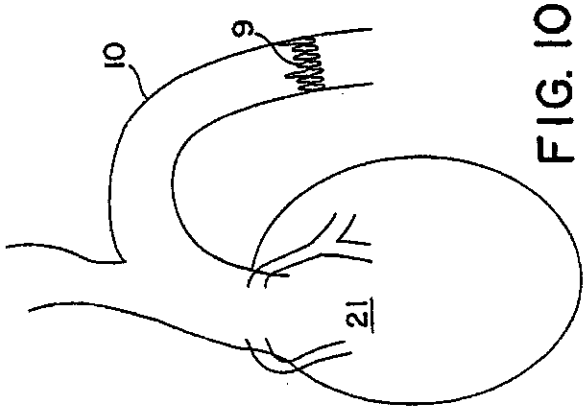

FIG. 10

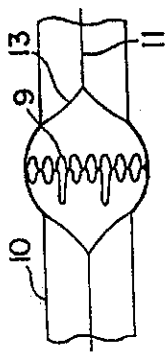

FIG. 6

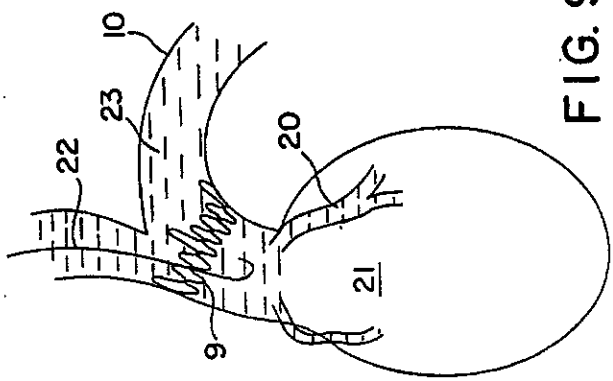

FIG. 9

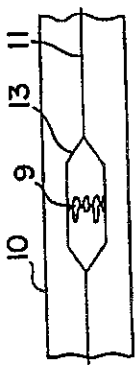

FIG. 5

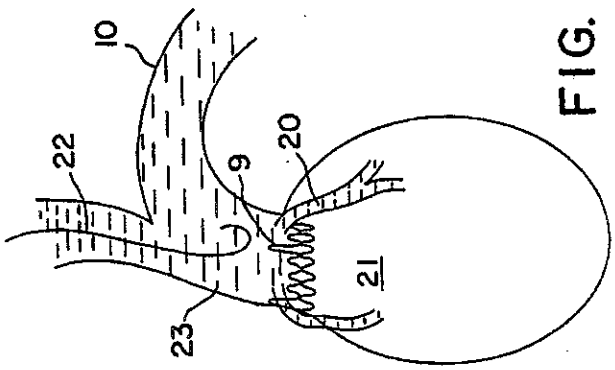

FIG. 8

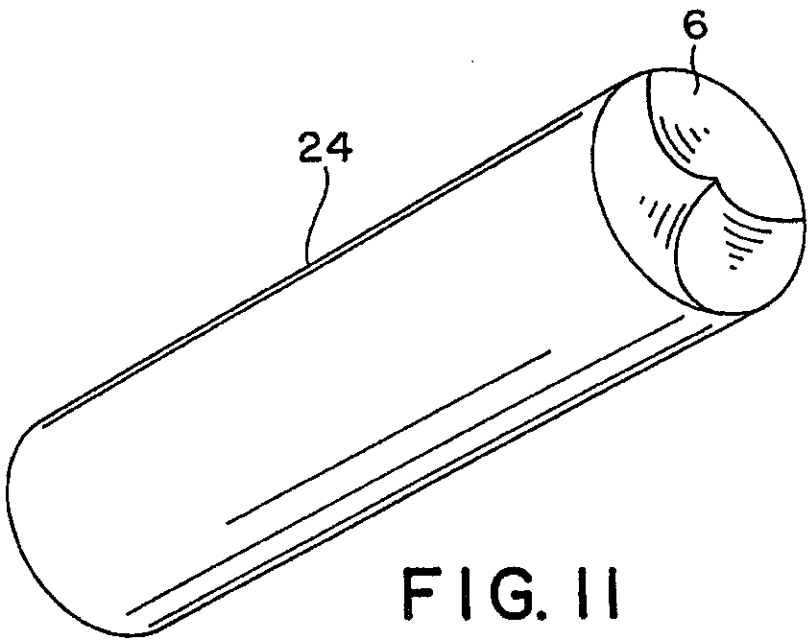

FIG. 11

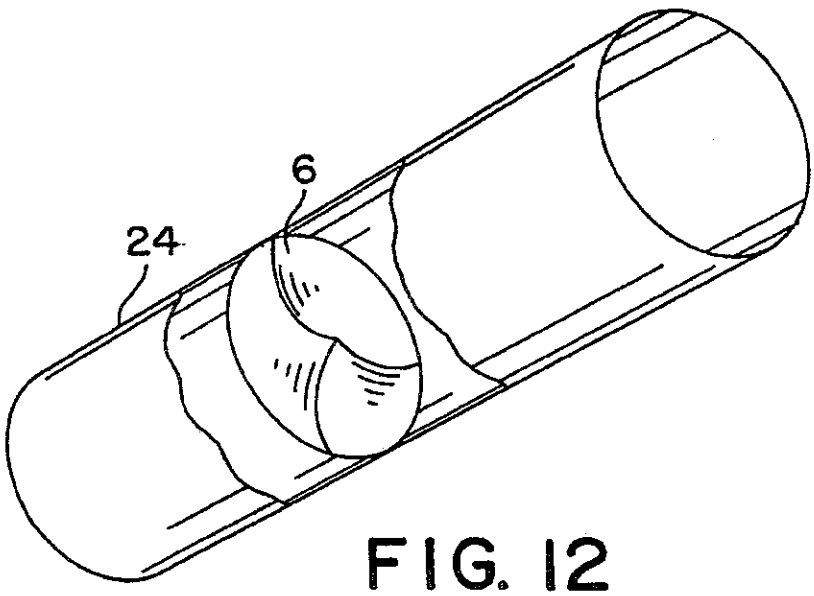

FIG. 12

VALVE PROSTHESIS FOR IMPLANTATION IN THE BODY

CROSS REFERENCE TO RELATED APPLICATION

This application is a continuation of application Ser. No. 08/955,228 filed Oct. 21, 1997, now abandoned, which is a division of application Ser. No. 08/801,036 filed Feb. 19, 1997, now U.S. Pat. No. 5,840,081, which is a continuation of application Ser. No. 08/352,127, filed Dec. 1, 1994, now abandoned, which is a divisional of Ser. No. 08/261,235, filed Jun. 14, 1994, now U.S. Pat. No. 5,411,552 which is a 371 of PCT/DK91/00134 filed Mar. 16, 1991.

BACKGROUND OF THE INVENTION

The present invention relates to a valve prosthesis, preferably a cardiac valve prosthesis, for implantation in the body and comprising a collapsible elastic valve which is mounted on an elastic stent wherein the commissural points of the elastic collapsible valve are mounted on the cylinder surface of the elastic stent.

Valve prostheses of this type are usually implanted in one of the channels of the body to replace a natural valve. In the present description the invention will be explained in connection with a cardiac valve prosthesis for implantation in aorta. However, it will be possible to use a valve prosthesis according to the invention in connection with implantation in other channels in the body by using the same technique as the one used for implantation of cardiac valve prosthesis. Such an implantation may, e.g., comprise the implantation of:

1. a valve (for instance a cardiac valve) in the veins,
2. a valve in the esophagus and at the stomach,
3. a valve in the ureter and/or the vesica,
4. a valve in the biliary passages,
5. a valve in the lymphatic system, and
6. a valve in the intestines.

An existing natural valve in the body is traditionally replaced with a valve prosthesis by a surgical implantation. However, a surgical implantation is often an exacting operation. Thus, today the implantation of cardiac valves are solely made by surgical technique where the thoracic cavity is opened. The operation calls for the use of a heart and lung machine for external circulation of the blood as the heart is stopped and opened during the surgical intervention and the artificial cardiac valves are subsequently sewed in.

Due to its exacting character, it is impossible to offer such operation to certain people. For instance, this is due to the fact that the person is physically weak because of age or illness. Moreover, the number of heart and lung machines available at a hospital will be a substantially limiting factor.

Cardiac valve prostheses that need no surgical intervention are known as there are used for implantation by means of a technique of catheterization. Examples of such valve prostheses are described in U.S. Pat. Nos. 3,671,979 and 4,056,854. However, both of these valve prostheses are connected to means which lead to the surface of the patient either for a subsequent activation of the valve or for a subsequent reposition or removal of the valve prosthesis. With these valve prostheses it is impossible to make an implantation which makes it possible for the patient to resume a substantially normal life in the same way as it is possible in connection with a surgical implantation of a cardiac valve.

From U.S. Pat. No. 3,755,823 an elastic stent for a cardiac valve prosthesis is known. However, this valve prostheses is not designed for implantation in the body by catheterization. Even though this patent contains no detailed explanation, the description indicates that this valve prosthesis is designed for implantation and sewing on by a surgical intervention.

Moreover, from U.S. Pat. Nos. 4,856,516 and 4,733,665 different shapes of expandable stents are known. These stents are made to be expanded by impression of a radially outward force coming from a balloon catheter or the like. These stents are made to reinforce the wall when there is a risk that the channel is closed and/or compressed.

The nearest prior art may be that the described in GB-A-2,056,023. This document discloses an elastic stent as described by way of introduction. Thus, the stent described comprises an elastic collapsible valve mounted on the cylinder surface of a cylindrical stent. However, the valve prosthesis including the stent is designated for mounting through a surgical intervention. Even though the stent is slightly collapsible, it will not be suited for implantation by a catheterization procedure.

SUMMARY OF THE INVENTION

It is the object of the present invention to provide a valve prosthesis of the type mentioned in the introductory part, which permits implantation without surgical intervention in the body and by using a catheter technique known per se and which makes it possible for the patient to resume a substantially normal life.

This is achieved according to the invention with a valve prosthesis of the type mentioned in the introductory part, which is characterized in that the stent is made from a radially collapsible and re-expandable cylindrical support means for folding and expanding together with the collapsible valve for implantation in the body by means of a technique of catheterization.

The collapsible elastic valve is mounted on the stent for instance by gluing, welding or by means of a number of suitable sutures.

If the support means are made from a thread structure, this can for instance be grate shaped, loop shaped or helical . This makes it possible to compress the stent and the collapsible valve mounted thereon for placing on the insertion catheter. The use of a non-self-expandable stent may, e.g., be effected by a compression of the stent around the expansion arrangement of the catheter which preferably consists of a balloon. When using a self-expandable stent, a catheter with an expansion arrangement is not used. In this case the stent is compressed and is inserted into an insertion or protection cap from which the stent is eliminated after implantation in order to obtain an expansion due to the stresses in the compressed support means, which for instance may be made from plastics or metal. After the compression the entire outer dimension is relatively small, which makes it possible to introduce the valve prostheses through a channel in the body.

When the valve prosthesis is introduced and placed correctly, the stent is expanded by self-expansion or by means of the expansion arrangement until the stent is given an outer dimension which is slightly larger than the channel in which it is placed. As the stent is elastic, a contraction of the stent is prevented once it is expanded. The stiffness in the material of the support means contributes to maintain the expanded shape of the stent. After the expansion is made, the expansion arrangement of the catheter is contracted and the catheter can be removed from the channel. The inlet opening can subsequently be closed and the patient will then be able to resume a normal life.

The valve prosthesis according to the invention does not require an actual operation but merely a small intervention

to optionally expose the body channel, e.g., a vein, through which the insertion takes place. Thus, patients for whom an operation would be associated with high risk can be offered implantation of, for instance, cardiac valves. After the implantation has taken place, the after-treatment will advantageously be shorter than normal, which means fewer hospital days for the patient. Moreover, it is assumed that it will be possible to implant the valve prosthesis under local anaesthetic.

The valve prosthesis can be used to replace a natural valve or to establish a new valve function in one of the channels in the body which do not naturally contain a valve. For instance this goes for veins (arteries and veins) on a place without natural valves. The function of the valve prosthesis is then to ensure that the blood flows in one direction only. The valve is meant to be used in veins in the legs of persons suffering from varicose veins (varices).

In persons having varicose veins the blood flows in a wrong direction, viz. from the central veins in the center of the leg towards the superficial veins. Among other things, this is due to the changed pressure in the legs, upright working position and other conditions. A valve prosthesis according to the invention may easily be placed in the veins and prevent the flow of the blood in a wrong direction.

Also, the valve prosthesis can be used in connection with diseases, for instance cancerous tumors, where too much humour is produced. If the humour is able to flow from the cancerous tumor through several channels, it is possible to drain the humour in one desired direction through the channels of the body by an appropriate placing of the valve prosthesis.

When the valve prosthesis is used as a cardiac valve prosthesis in the aorta, it is possible to mount it in three positions, viz., in the descending part of the aorta in a position between the coronary arteries and the left ventricle of the heart, or in the aorta in a position immediately after the mouth of the coronary arteries.

The cardiac valve prosthesis can also be used in other places than in the aorta. Thus, the valve prosthesis can be used in the pulmonary artery and/or the right ventricle of the heart for replacing the pulmonary valves. Likewise, the cardiac valve prosthesis can be used in the passage between the right auricle of the heart and the right ventricle of the heart (tricuspidalostium) and the passage between the left auricle of the heart and the left ventricle of the heart (mistralostium) for replacing the tricuspidal valve and the mitral valve, respectively.

Even though the cardiac valve preferably is meant to be used for patients suffering from aorta insufficiency and who cannot be offered an open heart surgery, the valve prosthesis can also be used for patents in connection with treatment of aorta stenosis. Several of the patients with aorta stenosis are elderly people who cannot be offered a surgical cardiac operation. The patients are offered balloon dilatation of the aorta stenosis which may result in an aorta insufficiency as a side effect of the treatment.

As to these patients it is possible to insert a valve prosthesis in the descending or ascending part of the aorta thoracalis a few days or weeks before the balloon dilatation. As a result thereof, the left ventricle is protected against weight if the subsequent balloon dilatation of the stenosis results in aorta insufficiency. In certain cases the weight (reflux) on the left ventricle is reduced by up to approximately 75%.

Furthermore, the stent may be made with a relatively great height and with a cylinder surface which is closed by a suitable material. Thus, a vascular prosthesis known per se is formed wherein the valve is mounted. This may facilitate the implantation of the valve prosthesis, for instance in the arcus aorta. Moreover, the great surface which abuts the inner wall of the channel contributes to ensure the securing of the valve prosthesis in the channel. This embodiment is also suitable as valve prosthesis which is inserted in veins. As veins have relatively thin and weaker walls than arteries, it is desirable that the valve prosthesis has a greater surface to distribute the outward pressure which is necessary to secure the valve prosthesis.

Moreover, the invention relates to a balloon catheter for implanting a valve prosthesis according to the invention and comprising a channel for injection of a fluid for the inflation of the balloon means of the catheter and an insertion cap wherein the balloon means of the catheter and a collapsible valve prosthesis mounted thereon are located during the injection, characterized in that the balloon means are provided with profiled surface which is made to ensure a steady fastening of the valve prosthesis during the withdrawal of the balloon means from the protection cap and the subsequent inflation for the expansion of the stent.

Different balloon catheters for implanting cores in the body are known. For instance, such balloon catheters are known from U.S. Pat. Nos. 4,856,516, 4,733,665 and 4,796.629 and from DE publication No. 2,246,526. However, the known balloon catheters have a smooth or a slightly wavy surface. The use of such balloon catheter is disadvantageous for mounting a valve prosthesis in a channel having a large flow as for instance the aorta. A large humour flow is able to displace the stent on the smooth surface of the balloon and makes an accurate positioning difficult. This drawback has been remedied with the balloon catheter according to the present invention as the profiled surface prevents a displacement of the valve prosthesis in relation to the balloon means during introduction and the subsequent inflation of the balloon means.

In connection with the implantation, any prior art technique may be used to supervise an accurate introduction and positioning of the valve prosthesis. Thus, guide wires for the catheter, X-ray supervision, injection of X-ray traceable liquids, ultrasonic measuring, etc. may be used.

DESCRIPTION OF THE DRAWINGS

The invention will now be explained in detail with reference to the accompanying schematical drawing, wherein

FIG. 1 shows a perspective view of a stent without a valve,

FIG. 2 is a perspective view of a valve prosthesis according to the invention made from the stent shown in FIG. 1 having a biological valve mounted thereon,

FIG. 3 is a partial view through the aorta illustrating a partially inflated balloon catheter,

FIG. 4 is a cross section through the embodiment shown in FIG. 9,

FIGS. 5–7 are views illustrating the introduction and implantation of a valve prosthesis of the invention in the aorta,

FIGS. 8–10 are views illustrating three possible positions of a cardiac valve prosthesis, and

FIGS. 11–12 are perspective views illustrating two further embodiments of a valve prosthesis having a closed cylindrical wall.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

FIG. 1 shows a stent 1 made by support means in the form of two 0.55 mm surgical stainless steel wires 2,3. The wires

are folded in 15 loops. Three loops 4 are 14 mm in height and are intended to secure the commissural points 5 (see FIG. 2) from a biological cardiac valve 6 which is mounted in the stent 1. The remaining loops have a height of 8 mm. These loops form circumferentially expandable sections 25 between the commissural points 5 forming commissural supports. Each of the two folded wires 2,3 is bent to form rings 7,8 which are closed by welding the ends. The two rings are placed on top of each other as will appear from FIG. 1 and they are mutually secured by means of a number of sutures (not shown). The lower ring is circumferentially expandable at least along sections thereof which correspond circumferentially expandable sections 25. By using a substantially cylindrical thread structure with projecting apices, a reduction in weight is obtained as compared to a stent which is exclusively cylindrical with the same loop heights for all the loops.

The biological valve 6 was removed from a slaughtered pig of 100 kg. The valve was cleaned before mounting in the stent 1. The cleaned valve has an outer diameter of 25–27 mm and the height of the three commissural points 5 is 8 mm. The valve 6 is mounted in the stent by means of a suitable number of sutures to form the cardiac valve prosthesis 9 shown in FIG. 2. The valve prosthesis produced is used for performing tests in pigs by implantation of cardiac valve prosthesis. However, the cardiac valve prosthesis for use in human beings has a corresponding form.

FIG. 3 shows a partial view through the aorta 10. A balloon catheter 11 is introduced in the aorta according to the direction of an arrow 12. In the Figure shown the balloon means 13 of the balloon catheter is led out of the protection cap 11 A and is partly inflated through a fluid channel 15, which is led to the surface of the patient. The balloon means 13 constitutes a tri-sectional balloon upon which the cardiac valve prosthesis is placed. In the form shown, the cardiac valve prosthesis is expanded exactly to be in contact with the aorta 10. The balloon means 13 is provided with three projecting beads 14 which are engaged with the one side of the cardiac valve prosthesis 9. The blood flowing through the aorta according to the direction of an arrow 16 will thus cause the cardiac valve prosthesis 9 to abut on the beads 14 and the valve cannot be displaced in relation to the balloon means 13. Moreover, the balloon catheter used comprises a central channel 17 to receive a guide wire 18 which is used in a way known per se for supervising the introduction of the catheter through fluoroscopi. In the shown embodiment beads 14 are only used at one side of the valve prosthesis, but, however, it will often be desirable to use the beads in pairs placed along lines parallel to the longitudinal axes 19 through the balloon means 13. In this case the spacing of the pair of beads 14 will correspond to the height of the loops of the stent. This makes it possible to make an effective fastening of a valve prosthesis on balloon means. Moreover, the fastening on the balloon means may be provided by using balloon means with an indentation in the surface (not shown).

FIG. 4 shows a cross section through the embodiment shown in FIG. 3 illustrating the placing of the beads 14 on the tri-sectional balloon means 13.

A balloon catheter of the above-described type which was used in tests of implanting of cardiac valve prosthesis 9 in pigs had the following dimensions. Each of the three balloons was 60 mm in length and 15 mm in diameter. The total diameter for the three inflated balloons was 31 mm and in the balloon catheter used two beads 14 having a height of 3 mm were mounted on each side of the three balloons. The beads had a spacing of 15 mm. The protection cap 11A of the balloon catheter had an outer diameter of 13.6 mm and an inner diameter of 12.5 mm and a length of 75 cm. The balloon catheter was provided with a standard guide wire having a diameter of 0.9 mm and a length 300 cm.

FIGS. 5–7 show the valve prosthesis 9 at different steps in introducing and implanting in the aorta 10 by means of the catheter 11 having the inflatable balloon means 13. The cardiac valve prosthesis 9 is initially placed above the deflated balloon means 13 and compressed manually around the balloon means (FIG. 5), whereafter the outer diameter for the valve prosthesis is approximately 10 mm. After the introduction and positioning, the balloon means 13 is inflated (FIG. 6), thereby contributing an outer dimension of approximately 30 mm to the cardiac valve prosthesis. To obtain an effective fastening in the aorta, the outer dimension of the cardiac valve prosthesis is greater than the diameter of the aorta. This means that the prosthesis is tight against the inner wall of the aorta with a pressure which is sufficiently large to counteract a detachment due to the flow of the blood. The balloon catheter 11 may subsequently be removed from the aorta 10 (FIG. 7). Due to the stiffness of the metal the valve prosthesis will prevent a contraction. However, smaller contractions may occur (<10% diameter reduction) after the deflation and removal of the balloon catheter 13. When the valve prosthesis is mounted as shown in FIG. 7, the patient will be able to resume a substantially normal life after a few days.

FIGS. 8–10 show the positioning of the valve prosthesis 9 as cardiac valve prosthesis in the aorta 10 in three different positions, i.e., in a position between the coronary arteries 20 and the left ventricle of the heart 21 (FIG. 8), in a position immediately after the mouth of the coronary arteries in the ascending part of the aorta (FIG. 9), and in a position in the descending part of the aorta 10. The positioning of the valve prosthesis is chosen in accordance with the diagnosis of the illness of the patient. By placing the cardiac valve prosthesis as shown in FIG. 8, there is a risk of detachment and/or covering the mouth of the coronary arteries, and therefore it is preferred to use a higher stent which, for instance, comprises several ranges placed on top of each other. This allows a fixation of the prosthesis at a place after the mouth of coronary arteries even though the valve itself is in the position between the coronary arteries and the left ventricle. FIGS. 8 and 9 show how a contrast medium 23 is injected by means of a so-called pigtail catheter 22 for registration of tightness of the implanted valve prosthesis 9.

A specific embodiment for a valve prosthesis and a balloon catheter for implanting the valve prosthesis has been explained above. However, it is obvious that it is possible to modify the valve prosthesis depending on the desired use, and moreover, it is possible to modify the catheter used in the implantation. Thus, the stent of the valve prosthesis may be made solely of one closed ring folded in a number of loops or with three or more mutually secured loop-shaped rings placed on top of each other. Moreover, it is possible to make the stent having a thread structure which instead of loops is grate shaped, helical or is formed otherwise if only it is ensured that the form of the stent permits the compression and expansion of the stent and fastening of the collapsible valve. Instead of a biological valve it might be possible to use other collapsible valves, such as valves made from synthetic materials, e.g., polyurethane. It is also possible to use valves with more or fewer flaps than three.

It is possible to make the valve prosthesis with a closed cylinder surface as illustrated in FIGS. 11 and 12. In both Figures the support means of the valve prosthesis is made of an elongated tubular means 24 having a closed cylinder

surface. This valve prosthesis is intended to expand by self-expansion or by means of a catheter according to the invention. This prosthesis is especially suitable for placing in veins and other channels where only a small pressure is exerted against the wall of the channel. In FIG. **11** the valve **6** is mounted at the end of the tubular means **24**. In FIG. **12** an embodiment is shown where the valve **6** is mounted in a central position in the tubular means **24**.

An explanation of a method of implanting a valve prosthesis according to the invention is given below:

a valve prosthesis **9** made of a stent **1** and a collapsible valve **6**, as described above, is placed on a deflated balloon means and is manually compressed thereon,

the balloon means **13** and the valve prosthesis are drawn into an insertion cover **11A**,

a guide wire **18** is inserted into the left ventricle of the heart through the central opening **17** of the balloon catheter under continuous fluoroscopi,

the insertion cover **11A** conveys the guide wire **18** to a point in the channel in the immediate vicinity of the desired position of the valve prosthesis,

the balloon means **13** is pushed out of the protection cap **11A** and the valve prosthesis is positioned in the desired position if necessary by use of further registration means to ensure an accurate positioning,

the balloon means **13** is inflated with a certain overstretching of the channel,

the balloon means **13** is deflated, and

the balloon means **13**, the guide wire **18** and the protection cap **11A** are drawn out and the opening in the channel, if any, wherein the valve prosthesis is inserted can be closed.

What is claimed is:

1. A method of endovascularly delivering a valve through a blood vessel, comprising the step of:

providing a tissue valve and a support structure, the support structure being movable from a collapsed shape to an expanded shape, the tissue valve being configured to permit blood flow in a direction and prevent blood flow in an opposite direction;

connecting the tissue valve to the support structure;

passing the support structure through a blood vessel with the support structure in the collapsed position; and

securing the tissue valve and the support structure to a desired valve location with the support structure in the expanded shape.

2. The method of claim **1**, wherein:

the providing step is carried out with the support structure comprising a ring.

3. The method of claim **2**, wherein:

the providing step is carried out with the ring being a cylinder.

4. The method of claim **2**, wherein:

the providing step is carried out with the support structure having at least one commissure support extending outwardly from the ring.

5. The method of claim **4**, wherein:

the providing step is carried out with the support structure comprising a wire.

6. The method of claim **5**, wherein:

the providing step is carried out with the wire forming a closed loop.

7. The method of claim **5**, wherein:

the providing step is carried out with the wire forming at least one commissure support extending outwardly from the ring.

8. The method of claim **1**, wherein:

the connecting step is carried out before the passing step.

9. The method of claim **1**, further comprising the step of:

expanding the support structure from the collapsed shape to the expanded shape before the securing step.

10. The method of claim **9**, wherein:

the expanding step is carried out by inflating a balloon so that the balloon moves the support structure from the collapsed shape to the expanded shape.

11. The method of claim **1**, wherein:

the passing step is carried out by coupling the support structure to a catheter.

12. The method of claim **1**, wherein:

the providing step is carried out with the tissue valve having three valve leaflets.

13. The method of claim **1**, wherein:

the passing step is carried out with the desired valve location being an artery.

14. The method of claim **13**, wherein:

the passing step is carried out with the desired valve location being the descending aorta.

15. The method of claim **1**, wherein:

the passing step is carried out with the desired valve location being the heart.

16. A method of endovascularly delivering a valve through a blood vessel, comprising the step of:

providing a valve having a support structure movable from a collapsed shape to an expanded shape, the valve being configured to permit blood flow in a direction and prevent blood flow in an opposite direction, the support structure having a ring with at least one commissure support extending from the ring, the commissure support supporting the valve;

passing the support structure through a vessel to a desired valve location with the support structure in the collapsed position;

expanding the support structure to the expanded shape with an expandable device thereby securing the valve to the desired valve location; and

removing the expandable device after the expanding step is completed thereby leaving the valve in the desired valve location.

17. The method of claim **16**, wherein:

the expanding step is carried out with the expandable device being an inflatable balloon.

18. The method of claim **16**, further comprising the step of:

mounting the support structure to the expandable device before the passing step.

19. The method of claim **16**, wherein:

the providing step is carried out with the support structure having a wire.

20. The method of claim **19**, wherein:

the providing step is carried out with the wire forming a closed loop.

21. The method of claim 16, wherein:

the providing step is carried out with the valve having a tissue portion mounted to the support structure.

22. The method of claim 16, wherein:

the expanding step is carried out so that the ring continuously engages the desired valve location.

23. The method of claim 16, wherein:

the passing step is carried out with the desired valve location being an artery.

24. The method of claim 23, wherein:

the passing step is carried out with the desired valve location being the descending aorta.

25. The method of claim 16, wherein:

the passing step is carried out with the desired valve location being the heart.

* * * * *

EXHIBIT 3

US006582462B1

(12) **United States Patent**
Andersen et al.

(10) **Patent No.: US 6,582,462 B1**
(45) **Date of Patent: *Jun. 24, 2003**

(54) **VALVE PROSTHESIS FOR IMPLANTATION IN THE BODY AND A CATHETER FOR IMPLANTING SUCH VALVE PROSTHESIS**

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(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

This patent is subject to a terminal disclaimer.

(21) Appl. No.: **09/514,426**

(22) Filed: **Feb. 28, 2000**

Related U.S. Application Data

(63) Continuation of application No. 09/026,574, filed on Feb. 20, 1998, now Pat. No. 6,168,614, which is a continuation of application No. 08/955,228, filed on Oct. 21, 1997, now abandoned, which is a division of application No. 08/801,036, filed on Feb. 19, 1997, now Pat. No. 5,840,081, which is a continuation of application No. 08/569,314, filed on Dec. 8, 1995, now abandoned, which is a continuation of application No. 08/352,127, filed on Dec. 1, 1994, now abandoned, which is a division of application No. 08/261,235, filed on Jun. 14, 1994, now Pat. No. 5,411,552, which is a continuation of application No. 07/961,891, filed as application No. PCT/DK91/00134 on Mar. 16, 1991, now abandoned.

(30) **Foreign Application Priority Data**

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(58) **Field of Search** 623/FOR 101, 623/2.1–2.19, 2.38–2.41, 900, 904, 1.24–1.26

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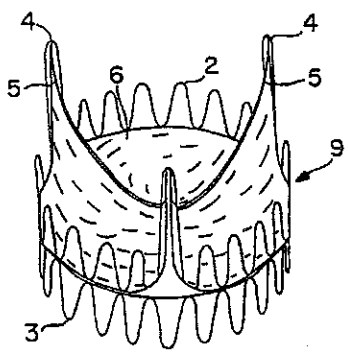
(57) **ABSTRACT**

A valve prosthesis for implantation in the body by use of a catheter includes a stent made from an expandable cylinder-shaped thread structure having several spaced apices. The elastically collapsible valve is mounted on the stent as the commissural points of the valve are secured to the projecting apices.

8 Claims, 4 Drawing Sheets



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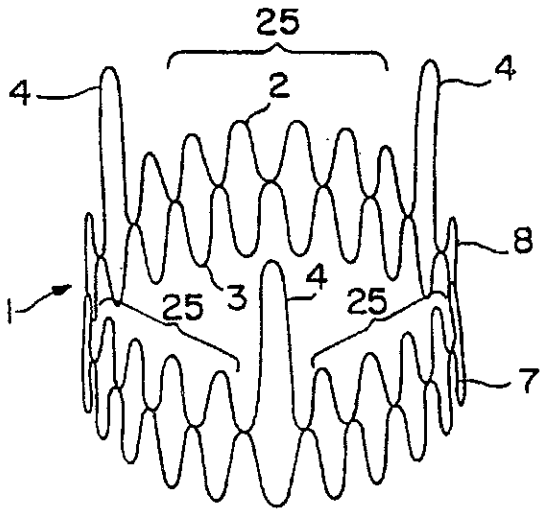

FIG. 1

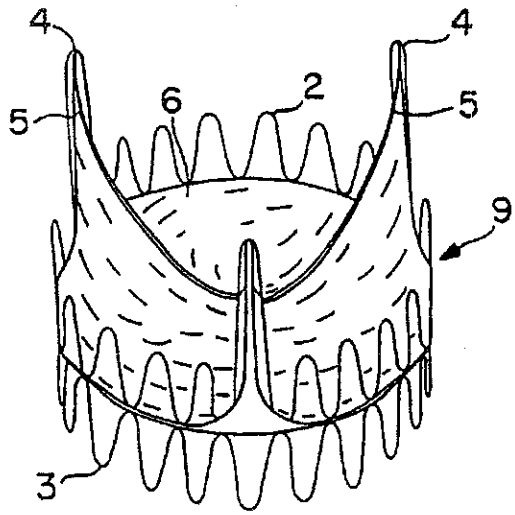

FIG. 2

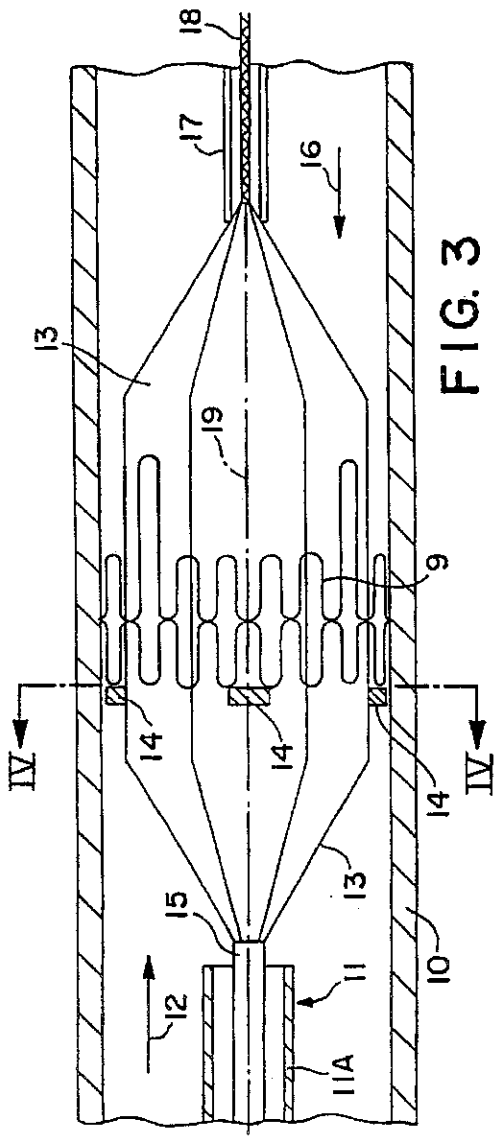

FIG. 3

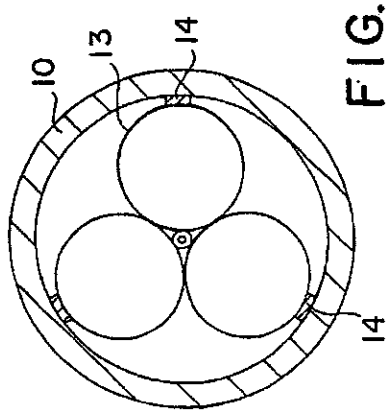

FIG. 4

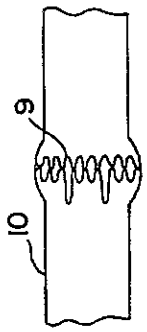

FIG. 7

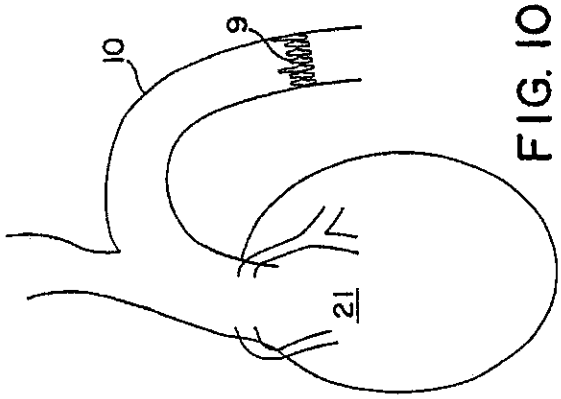

FIG. 10

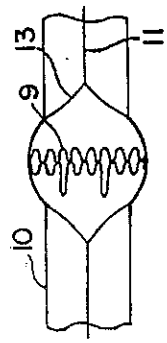

FIG. 6

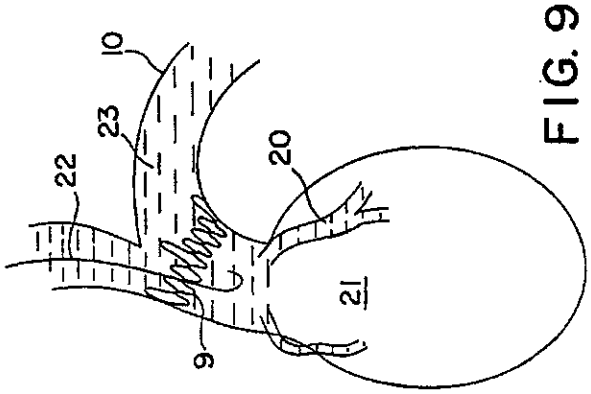

FIG. 9

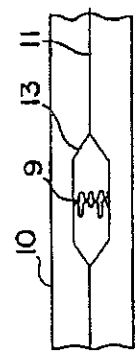

FIG. 5

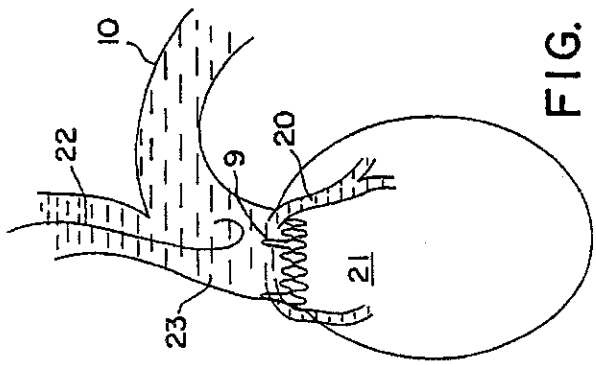

FIG. 8

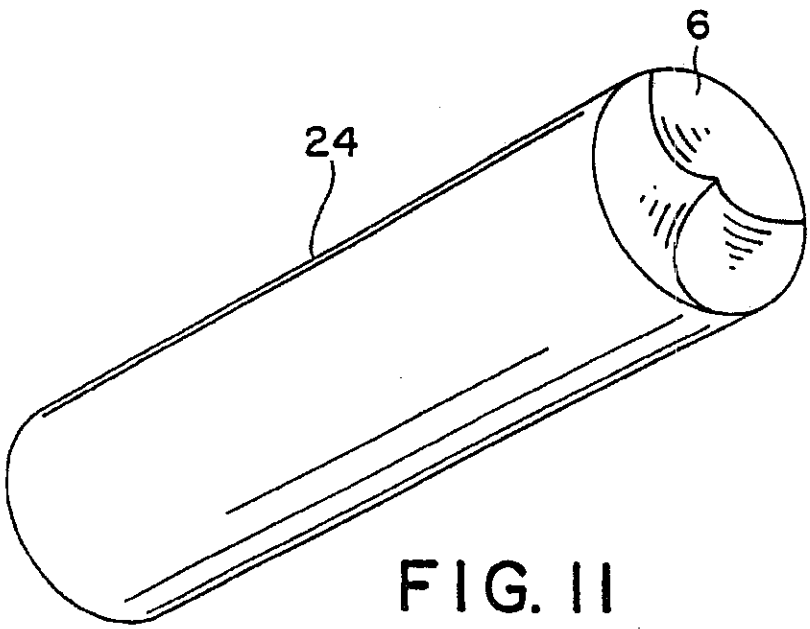

FIG. 11

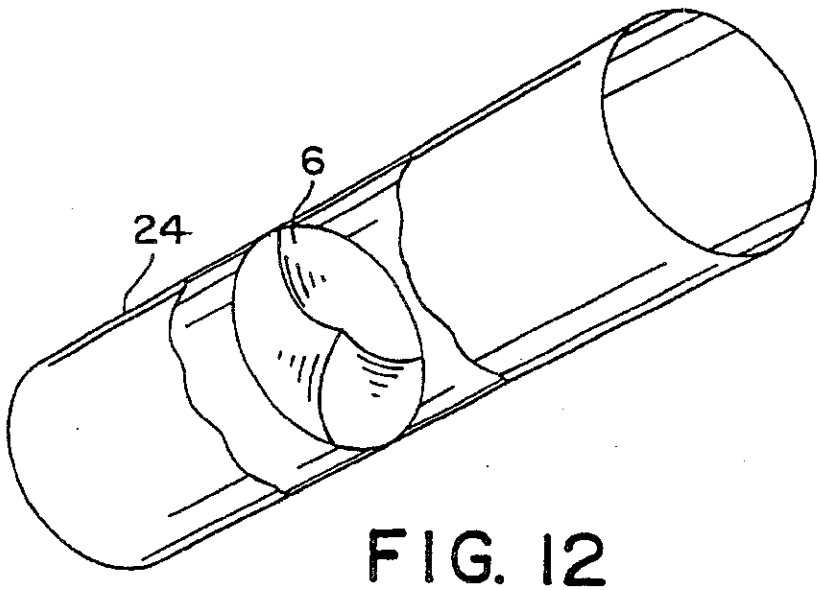

FIG. 12

VALVE PROSTHESIS FOR IMPLANTATION IN THE BODY AND A CATHETER FOR IMPLANTING SUCH VALVE PROSTHESIS

CROSS REFERENCE TO RELATED APPLICATION

This application is a continuation of application Ser. No. 09/026,574, filed Feb. 20, 1998, now U.S. Pat. No. 6,168,614, which is a continuation of application Ser. No. 08/955,228, filed Oct. 21, 1997, now abandoned, which is a division of application Ser. No. 08/801,036, filed Feb. 19, 1997, now U.S. Pat. No. 5,840,081, which is a continuation of application Ser. No. 08/569,314, filed Dec. 8, 1995, now abandoned, which is a continuation of application Ser. No. 08/352,127, filed Dec. 1, 1994, now abandoned, which is a division of application Ser. No. 08/261,235, filed Jun. 14, 1994, now U.S. Pat. No. 5,411,552, which is a continuation of application Ser. No. 07/961,891, filed Jan. 11, 1993, now abandoned which is based on PCT/DK91/00134, filed Mar. 16, 1991.

BACKGROUND OF THE INVENTION

The present invention relates to a valve prosthesis, preferably a cardiac valve prosthesis, for implantation in the body and comprising a collapsible elastic valve which is mounted on an elastic stent wherein the commissural points of the elastic collapsible valve are mounted on the cylinder surface of the elastic stent.

Valve prostheses of this type are usually implanted in one of the channels of the body to replace a natural valve. In the present description the invention will be explained in connection with a cardiac valve prosthesis for implantation in aorta. However, it will be possible to use a valve prosthesis according to the invention in connection with implantation in other channels in the body by using the same technique as the one used for implantation of cardiac valve prosthesis. Such an implantation may, e.g., comprise the implantation of:

1. a valve (for instance a cardiac valve) in the veins,
2. a valve in the esophagus and at the stomach,
3. a valve in the ureter and/or the vesica,
4. a valve in the biliary passages,
5. a valve in the lymphatic system, and
6. a valve in the intestines.

An existing natural valve in the body is traditionally replaced with a valve prosthesis by a surgical implantation. However, a surgical implantation is often an exacting operation. Thus, today the implantation of cardiac valves are solely made by surgical technique where the thoracic cavity is opened. The operation calls for the use of a heart and lung machine for external circulation of the blood as the heart is stopped and opened during the surgical intervention and the artificial cardiac valves are subsequently sewed in.

Due to its exacting character, it is impossible to offer such operation to certain people. For instance, this is due to the fact that the person is physically weak because of age or illness. Moreover, the number of heart and lung machines available at a hospital will be a substantially limiting factor.

Cardiac valve prostheses that need no surgical intervention are known as there are used for implantation by means of a technique of catheterization. Examples of such valve prostheses are described in U.S. Pat. Nos. 3,671,979 and 4,056,854. However, both of these valve prostheses are connected to means which lead to the surface of the patient either for a subsequent activation of the valve or for a

subsequent reposition or removal of the valve prosthesis. With these valve prostheses it is impossible to make an implantation which makes it possible for the patient to resume a substantially normal life in the same way as it is possible in connection with a surgical implantation of a cardiac valve.

From U.S. Pat. No. 3,755,823 an elastic stent for a cardiac valve prosthesis is known. However, this valve prostheses is not designed for implantation in the body by catheterization. Even though this patent contains no detailed explanation, the description indicates that this valve prosthesis is designed for implantation and sewing on by a surgical intervention.

Moreover, from U.S. Pat. Nos. 4,856,516 and 4,733,665 different shapes of expandable stents are known. These stents are made to be expanded by impression of a radially outward force coming from a balloon catheter or the like. These stents are made to reinforce the wall when there is a risk that the channel is closed and/or compressed.

The nearest prior art may be that the described in GB-A-2.056,023. This document discloses an elastic stent as described by way of introduction. Thus, the stent described comprises an elastic collapsible valve mounted on the cylinder surface of a cylindrical stent. However, the valve prosthesis including the stent is designated for mounting through a surgical intervention. Even though the stent is slightly collapsible, it will not be suited for implantation by a catheterization procedure.

SUMMARY OF THE INVENTION

It is the object of the present invention to provide a valve prosthesis of the type mentioned in the introductory part, which permits implantation without surgical intervention in the body and by using a catheter technique known per se and which makes it possible for the patient to resume a substantially normal life.

This is achieved according to the invention with a valve prosthesis of the type mentioned in the introductory part, which is characterized in that the stent is made from a radially collapsible and re-expandable cylindrical support means for folding and expanding together with the collapsible valve for implantation in the body by means of a technique of catheterization.

The collapsible elastic valve is mounted on the stent for instance by gluing, welding or by means of a number of suitable sutures.

If the support means are made from a thread structure, this can for instance be grate shaped, loop shaped or helical. This makes it possible to compress the stent and the collapsible valve mounted thereon for placing on the insertion catheter. The use of a non-self-expandable stent may, e.g., be effected by a compression of the stent around the expansion arrangement of the catheter which preferably consists of a balloon. When using a self-expandable stent, a catheter with an expansion arrangement is not used. In this case the stent is compressed and is inserted into an insertion or protection cap from which the stent is eliminated after implantation in order to obtain an expansion due to the stresses in the compressed support means, which for instance may be made from plastics or metal. After the compression the entire outer dimension is relatively small, which makes it possible to introduce the valve prostheses through a channel in the body.

When the valve prosthesis is introduced and placed correctly, the stent is expanded by self-expansion or by means of the expansion arrangement until the stent is given an outer dimension which is slightly larger than the channel in which it is placed. As the stent is elastic, a contraction of

the stent is prevented once it is expanded. The stiffness in the material of the support means contributes to maintain the expanded shape of the stent. After the expansion is made, the expansion arrangement of the catheter is contracted and the catheter can be removed from the channel. The inlet opening can subsequently be closed and the patient will then be able to resume a normal life.

The valve prosthesis according to the invention does not require an actual operation but merely a small intervention to optionally expose the body channel, e.g., a vein, through which the insertion takes place. Thus, patients for whom an operation would be associated with high risk can be offered implantation of, for instance, cardiac valves. After the implantation has taken place, the after-treatment will advantageously be shorter than normal, which means fewer hospital days for the patient. Moreover, it is assumed that it will be possible to implant the valve prosthesis under local anaesthetic.

The valve prosthesis can be used to replace a natural valve or to establish a new valve function in one of the channels in the body which do not naturally contain a valve. For instance this goes for veins (arteries and veins) on a place without natural valves. The function of the valve prosthesis is then to ensure that the blood flows in one direction only. The valve is meant to be used in veins in the legs of persons suffering from varicose veins (varices).

In persons having varicose veins the blood flows in a wrong direction, viz. from the central veins in the center of the leg towards the superficial veins. Among other things, this is due to the changed pressure in the legs, upright working position and other conditions. A valve prosthesis according to the invention may easily be placed in the veins and prevent the flow of the blood in a wrong direction.

Also, the valve prosthesis can be used in connection with diseases, for instance cancerous tumors, where too much humour is produced. If the humour is able to flow from the cancerous tumor through several channels, it is possible to drain the humour in one desired direction through the channels of the body by an appropriate placing of the valve prosthesis.

When the valve prosthesis is used as a cardiac valve prosthesis in the aorta, it is possible to mount it in three positions, viz., in the descending part of the aorta in a position between the coronary arteries and the left ventricle of the heart, or in the aorta in a position immediately after the mouth of the coronary arteries.

The cardiac valve prosthesis can also be used in other places than in the aorta. Thus, the valve prosthesis can be used in the pulmonary artery and/or the right ventricle of the heart for replacing the pulmonary valves. Likewise, the cardiac valve prosthesis can be used in the passage between the right auricle of the heart and the right ventricle of the heart (tricuspidalostium) and the passage between the left auricle of the heart and the left ventricle of the heart (mistralostium) for replacing the tricuspidal valve and the mitral valve, respectively.

Even though the cardiac valve preferably is meant to be used for patients suffering from aorta insufficiency and who cannot be offered an open heart surgery, the valve prosthesis can also be used for patents in connection with treatment of aorta stenosis. Several of the patients with aorta stenosis are elderly people who cannot be offered a surgical cardiac operation. The patients are offered balloon dilatation of the aorta stenosis which may result in an aorta insufficiency as a side effect of the treatment.

As to these patients it is possible to insert a valve prosthesis in the descending or ascending part of the aorta thoracalis a few days or weeks before the balloon dilatation. As a result thereof, the left ventricle is protected against weight if the subsequent balloon dilatation of the stenosis results in aorta insufficiency. In certain cases the weight (reflux) on the left ventricle is reduced by up to approximately 75%.

Furthermore, the stent may be made with a relatively great height and with a cylinder surface which is closed by a suitable material. Thus, a vascular prosthesis known per se is formed wherein the valve is mounted. This may facilitate the implantation of the valve prosthesis, for instance in the arcus aorta. Moreover, the great surface which abuts the inner wall of the channel contributes to ensure the securing of the valve prosthesis in the channel. This embodiment is also suitable as valve prosthesis which is inserted in veins. As veins have relatively thin and weaker walls than arteries, it is desirable that the valve prosthesis has a greater surface to distribute the outward pressure which is necessary to secure the valve prosthesis.

Moreover, the invention relates to a balloon catheter for implanting a valve prosthesis according to the invention and comprising a channel for injection of a fluid for the inflation of the balloon means of the catheter and an insertion cap wherein the balloon means of the catheter and a collapsible valve prosthesis mounted thereon are located during the injection, characterized in that the balloon means are provided with profiled surface which is made to ensure a steady fastening of the valve prosthesis during the withdrawal of the balloon means from the protection cap and the subsequent inflation for the expansion of the stent.

Different balloon catheters for implanting cores in the body are known. For instance. such balloon catheters are known from U.S. Pat. Nos. 4,856,516, 4,733,665 and 4,796,629 and from DE publication No. 2,246,526. However, the known balloon catheters have a smooth or a slightly wavy surface. The use of such balloon catheter is disadvantageous for mounting a valve prosthesis in a channel having a large flow as for instance the aorta. A large humour flow is able to displace the stent on the smooth surface of the balloon and makes an accurate positioning difficult. This drawback has been remedied with the balloon catheter according to the present invention as the profiled surface prevents a displacement of the valve prosthesis in relation to the balloon means during introduction and the subsequent inflation of the balloon means.

In connection with the implantation, any prior art technique may be used to supervise an accurate introduction and positioning of the valve prosthesis. Thus, guide wires for the catheter, X-ray supervision, injection of X-ray traceable liquids, ultrasonic measuring, etc. may be used.

DESCRIPTION OF THE DRAWINGS

The invention will now be explained in detail with reference to the accompanying schematical drawing, wherein

FIG. 1 shows a perspective view of a stent without a valve,

FIG. 2 is a perspective view of a valve prosthesis according to the invention made from the stent shown in FIG. 1 having a biological valve mounted thereon,

FIG. 3 is a partial view through the aorta illustrating a partially inflated balloon catheter,

FIG. 4 is a cross section through the embodiment shown in FIG. 9,

FIGS. 5–7 are views illustrating the introduction and implantation of a valve prosthesis of the invention in the aorta,

FIGS. 8–10 are views illustrating three possible positions of a cardiac valve prosthesis, and

FIGS. 11–12 are perspective views illustrating two further embodiments of a valve prosthesis having a closed cylindrical wall.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

FIG. 1 shows a stent 1 made by support means in the form of two 0.55 mm surgical stainless steel wires 2,3. The wires are folded in 15 loops. Three loops 4 are 14 mm in height and are intended to secure the commissural points 5 (see FIG. 2) from a biological cardiac valve 6 which is mounted in the stent 1. The remaining loops have a height of 8 mm. These loops form circumferentially expandable sections 25 between the commissural points 5 forming commissural supports. Each of the two folded wires 2,3 is bent to form rings 7,8 which are closed by welding the ends. The two rings are placed on top of each other as will appear from FIG. 1 and they are mutually secured by means of a number of sutures (not shown). The lower ring is circumferentially expandable at least along sections thereof which correspond to the circumferentially expandable sections 25. By using a substantially cylindrical thread structure with projecting apices. a reduction in weight is obtained as compared to a stent which is exclusively cylindrical with the same loop heights for all the loops.

The biological valve 6 was removed from a slaughtered pig of 100 kg. The valve was cleaned before mounting in the stent 1. The cleaned valve has an outer diameter of 25–27 mm and the height of the three commissural points 5 is 8 mm. The valve 6 is mounted in the stent by means of a suitable number of sutures to form the cardiac valve prosthesis 9 shown in FIG. 2. The valve prosthesis produced is used for performing tests in pigs by implantation of cardiac valve prosthesis. However, the cardiac valve prosthesis for use in human beings has a corresponding form.

FIG. 3 shows a partial view through the aorta 10. A balloon catheter 11 is introduced in the aorta according to the direction of an arrow 12. In the Figure shown the balloon means 13 of the balloon catheter is led out of the protection cap 11A and is partly inflated through a fluid channel 15, which is led to the surface of the patient. The balloon means 13 constitutes a tri-sectional balloon upon which the cardiac valve prosthesis is placed. In the form shown, the cardiac valve prosthesis is expanded exactly to be in contact with the aorta 10. The balloon means 13 is provided with three projecting beads 14 which are engaged with the one side of the cardiac valve prosthesis 9. The blood flowing through the aorta according to the direction of an arrow 16 will thus cause the cardiac valve prosthesis 9 to abut on the beads 14 and the valve cannot be displaced in relation to the balloon means 13. Moreover, the balloon catheter used comprises a central channel 17 to receive a guide wire 18 which is used in a way known per se for supervising the introduction of the catheter through fluoroscopi. In the shown embodiment beads 14 are only used at one side of the valve prosthesis, but, however, it will often be desirable to use the beads in pairs placed along lines parallel to the longitudinal axes 19 through the balloon means 13. In this case the spacing of the pair of beads 14 will correspond to the height of the loops of the stent. This makes it possible to make an effective fastening of a valve prosthesis on balloon means. Moreover, the fastening on the balloon means may be provided by using balloon means with an indentation in the surface (not shown).

FIG. 4 shows a cross section through the embodiment shown in FIG. 3 illustrating the placing of the beads 14 on the tri-sectional balloon means 13.

A balloon catheter of the above-described type which was used in tests of implanting of cardiac valve prosthesis 9 in pigs had the following dimensions. Each of the three balloons was 60 mm in length and 15 mm in diameter. The total diameter for the three inflated balloons was 31 mm and in the balloon catheter used two beads 14 having a height of 3 mm were mounted on each side of the three balloons. The beads had a spacing of 15 mm. The protection cap 11A of the balloon catheter had an outer diameter of 13.6 mm and an inner diameter of 12.5 mm and a length of 75 cm. The balloon catheter was provided with a standard guide wire having a diameter of 0.9 mm and a length 300 cm.

FIGS. 5–7 show the valve prosthesis 9 at different steps in introducing and implanting in the aorta 10 by means of the catheter 11 having the inflatable balloon means 13. The cardiac valve prosthesis 9 is initially placed above the deflated balloon means 13 and compressed manually around the balloon means (FIG. 5), whereafter the outer diameter for the valve prosthesis is approximately 10 mm. After the introduction and positioning, the balloon means 13 is inflated (FIG. 6), thereby contributing an outer dimension of approximately 30 mm to the cardiac valve prosthesis. To obtain an effective fastening in the aorta, the outer dimension of the cardiac valve prosthesis is greater than the diameter of the aorta. This means that the prosthesis is tight against the inner wall of the aorta with a pressure which is sufficiently large to counteract a detachment due to the flow of the blood. The balloon catheter 11 may subsequently be removed from the aorta 10 (FIG. 7). Due to the stiffness of the metal the valve prosthesis will prevent a contraction. However, smaller contractions may occur (<10% diameter reduction) after the deflation and removal of the balloon catheter 13. When the valve prosthesis is mounted as shown in FIG. 7, the patient will be able to resume a substantially normal life after a few days.

FIGS. 8–10 show the positioning of the valve prosthesis 9 as cardiac valve prosthesis in the aorta 10 in three different positions, i.e., in a position between the coronary arteries 20 and the left ventricle of the heart 21 (FIG. 8), in a position immediately after the mouth of the coronary arteries in the ascending part of the aorta (FIG. 9), and in a position in the descending part of the aorta 10. The positioning of the valve prosthesis is chosen in accordance with the diagnosis of the illness of the patient. By placing the cardiac valve prosthesis as shown in FIG. 8, there is a risk of detachment and/or covering the mouth of the coronary arteries, and therefore it is preferred to use a higher stent which, for instance, comprises several ranges placed on top of each other. This allows a fixation of the prosthesis at a place after the mouth of coronary arteries even though the valve itself is in the position between the coronary arteries and the left ventricle. FIGS. 8 and 9 show how a contrast medium 23 is injected by means of a so-called pigtail catheter for registration of tightness of the implanted valve prosthesis 9.

A specific embodiment for a valve prosthesis and a balloon catheter for implanting the valve prosthesis has been explained above. However, it is obvious that it is possible to modify the valve prosthesis depending on the desired use, and moreover, it is possible to modify the catheter used in the implantation. Thus, the stent of the valve prosthesis may be made solely of one closed ring folded in a number of loops or with three or more mutually secured loop-shaped rings placed on top of each other. Moreover, it is possible to make the stent having a thread structure which instead of

loops is grate shaped, helical or is formed otherwise if only it is ensured that the form of the stent permits the compression and expansion of the stent and fastening of the collapsible valve. Instead of a biological valve it might be possible to use other collapsible valves, such as valves made from synthetic materials, e.g., polyurethane. It is also possible to use valves with more or fewer flaps than three.

It is possible to make the valve prosthesis with a closed cylinder surface as illustrated in FIGS. **11** and **12**. In both Figures the support means of the valve prosthesis is made of an elongated tubular means **24** having a closed cylinder surface. This valve prosthesis is intended to expand by self-expansion or by means of a catheter according to the invention. This prosthesis is especially suitable for placing in veins and other channels where only a small pressure is exerted against the wall of the channel. In FIG. **11** the valve **6** is mounted at the end of the tubular means **24**. In FIG. **12** an embodiment is shown where the valve **6** is mounted in a central position in the tubular means **24**.

An explanation of a method of implanting a valve prosthesis according to the invention is given below:

- a valve prosthesis **9** made of a stent **1** and a collapsible valve **6**, as described above, is placed on a deflated balloon means and is manually compressed thereon,
- the balloon means **13** and the valve prosthesis are drawn into an insertion cover **11**A,
- a guide wire **18** is inserted into the left ventricle of the heart through the central opening **17** of the balloon catheter under continuous fluoroscopi,
- the insertion cover **11**A conveys the guide wire **18** to a point in the channel in the immediate vicinity of the desired position of the valve prosthesis,
- the balloon means **13** is pushed out of the protection cap **11**A and the valve prosthesis is positioned in the desired position if necessary by use of further registration means to ensure an accurate positioning,
- the balloon means **13** is inflated with a certain overstretching of the channel,
- the balloon means **13** is deflated, and
- the balloon means **13**, the guide wire **18** and the protection cap **11**A are drawn out and the opening in the channel, if any, wherein the valve prosthesis is inserted can be closed.

What is claimed is:

1. A valve prosthesis for implantation in a body channel having an inner wall, the prosthesis comprising;

a radially collapsible and expandable cylindrical stent, the stent including a cylindrical support means having a cylinder surface; and

a collapsible and expandable valve having commissural points, the valve mounted to the stent at the commissural points, wherein the stent and valve are configured to be implanted in the body by way of catheterization.

2. The valve prosthesis according to claim **1**, wherein the support means is made of thread structure.

3. The valve prosthesis according to claim **2**, wherein the thread structure comprises several spaced apices that extend from one end of the cylindrical support means in a direction along a longitudinal axis of the cylindrical support means, the commissural points of the valve being attached to the apices.

4. The valve prosthesis according to claim **3**, wherein the collapsible valve is a biologically trilobate valve.

5. The valve prosthesis according to claim **1**, wherein the stent comprises at least two closed rings, each formed from more than three loops, the rings connected one to another, and wherein three of the loops in at least one of the rings has a greater height than the remaining loops.

6. The valve prosthesis according to claim **5**, wherein each of the rings of the stent is made from a wire having a diameter of 0.05 mm and a loop height of approximately 8 mm and approximately 14 mm for the three greater height loops, and that the cylindrical wire structure produced and the collapsible valve mounted thereon in a folded state have an outer diameter of approximately 10 mm and in an expanded state an outer diameter of approximately 30 mm.

7. The valve prosthesis according to claim **5**, wherein three or more mutually attached rings placed on top of each other are used in that the stent is made to be fixed through the expansion at one point in the channel where the valve prosthesis is inserted, which point is different from the point where the valve is mounted in the stent.

8. The valve prosthesis according to claim **1**, wherein the cylinder surface of the support means is closed to form a tubular element.

* * * * *

JS 44 (Rev. 11/04)

CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. (SEE INSTRUCTIONS ON THE REVERSE OF THE FORM.)

I. (a) PLAINTIFFS
Edwards Lifesciences AG and
Edwards Lifesciences LLC

(b) County of Residence of First Listed Plaintiff _____
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorney's (Firm Name, Address, and Telephone Number)
Jack B. Blumenfeld, MORRIS, NICHOLS, ARSHT & TUNNELL LLP,
1201 North Market Street, P.O. Box 1347,
Wilmington, DE 19899-1347, (302) 658-9200

DEFENDANTS
CoreValve, Inc.

County of Residence of First Listed Defendant _____
(IN U.S. PLAINTIFF CASES ONLY)
NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE LAND INVOLVED.

Attorneys (If Known)

II. BASIS OF JURISDICTION (Place an "X" in One Box Only)

- ☐ 1 U.S. Government Plaintiff
- ☒ 3 Federal Question (U.S. Government Not a Party)
- ☐ 2 U.S. Government Defendant
- ☐ 4 Diversity (Indicate Citizenship of Parties in Item III)

III. CITIZENSHIP OF PRINCIPAL PARTIES (Place an "X" in One Box for Plaintiff and One Box for Defendant)
(For Diversity Cases Only)

	PTF	DEF		PTF	DEF
Citizen of This State	☐ 1	☐ 1	Incorporated *or* Principal Place of Business In This State	☐ 4	☐ 4
Citizen of Another State	☐ 2	☐ 2	Incorporated *and* Principal Place of Business In Another State	☐ 5	☐ 5
Citizen or Subject of a Foreign Country	☐ 3	☐ 3	Foreign Nation	☐ 6	☐ 6

IV. NATURE OF SUIT (Place an "X" in One Box Only)

CONTRACT	TORTS		FORFEITURE/PENALTY	BANKRUPTCY	OTHER STATUTES
☐ 110 Insurance	PERSONAL INJURY	PERSONAL INJURY	☐ 610 Agriculture	☐ 422 Appeal 28 USC 158	☐ 400 State Reapportionment
☐ 120 Marine	☐ 310 Airplane	☐ 362 Personal Injury - Med. Malpractice	☐ 620 Other Food & Drug	☐ 423 Withdrawal 28 USC 157	☐ 410 Antitrust
☐ 130 Miller Act	☐ 315 Airplane Product Liability	☐ 365 Personal Injury - Product Liability	☐ 625 Drug Related Seizure of Property 21 USC 881	PROPERTY RIGHTS	☐ 430 Banks and Banking
☐ 140 Negotiable Instrument	☐ 320 Assault, Libel & Slander	☐ 368 Asbestos Personal Injury Product Liability	☐ 630 Liquor Laws	☐ 820 Copyrights	☐ 450 Commerce
☐ 150 Recovery of Overpayment & Enforcement of Judgment	☐ 330 Federal Employers' Liability	PERSONAL PROPERTY	☐ 640 R.R. & Truck	☒ 830 Patent	☐ 460 Deportation
☐ 151 Medicare Act	☐ 340 Marine	☐ 370 Other Fraud	☐ 650 Airline Regs.	☐ 840 Trademark	☐ 470 Racketeer Influenced and Corrupt Organizations
☐ 152 Recovery of Defaulted Student Loans (Excl. Veterans)	☐ 345 Marine Product Liability	☐ 371 Truth in Lending	☐ 660 Occupational Safety/Health		☐ 480 Consumer Credit
☐ 153 Recovery of Overpayment of Veteran's Benefits	☐ 350 Motor Vehicle	☐ 380 Other Personal Property Damage	☐ 690 Other		☐ 490 Cable/Sat TV
☐ 160 Stockholders' Suits	☐ 355 Motor Vehicle Product Liability	☐ 385 Property Damage Product Liability	LABOR	SOCIAL SECURITY	☐ 810 Selective Service
☐ 190 Other Contract	☐ 360 Other Personal Injury		☐ 710 Fair Labor Standards Act	☐ 861 HIA (1395ff)	☐ 850 Securities/Commodities/ Exchange
☐ 195 Contract Product Liability			☐ 720 Labor/Mgmt. Relations	☐ 862 Black Lung (923)	☐ 875 Customer Challenge 12 USC 3410
☐ 196 Franchise			☐ 730 Labor/Mgmt.Reporting & Disclosure Act	☐ 863 DIWC/DIWW (405(g))	☐ 890 Other Statutory Actions
REAL PROPERTY	CIVIL RIGHTS	PRISONER PETITIONS	☐ 740 Railway Labor Act	☐ 864 SSID Title XVI	☐ 891 Agricultural Acts
☐ 210 Land Condemnation	☐ 441 Voting	☐ 510 Motions to Vacate Sentence	☐ 790 Other Labor Litigation	☐ 865 RSI (405(g))	☐ 892 Economic Stabilization Act
☐ 220 Foreclosure	☐ 442 Employment	Habeas Corpus:	☐ 791 Empl. Ret. Inc. Security Act	FEDERAL TAX SUITS	☐ 893 Environmental Matters
☐ 230 Rent Lease & Ejectment	☐ 443 Housing/ Accommodations	☐ 530 General		☐ 870 Taxes (U.S. Plaintiff or Defendant)	☐ 894 Energy Allocation Act
☐ 240 Torts to Land	☐ 444 Welfare	☐ 535 Death Penalty		☐ 871 IRS—Third Party 26 USC 7609	☐ 895 Freedom of Information Act
☐ 245 Tort Product Liability	☐ 445 Amer. w/Disabilities - Employment	☐ 540 Mandamus & Other			☐ 900Appeal of Fee Determination Under Equal Access to Justice
☐ 290 All Other Real Property	☐ 446 Amer. w/Disabilities - Other	☐ 550 Civil Rights			☐ 950 Constitutionality of State Statutes
	☐ 440 Other Civil Rights	☐ 555 Prison Condition			

V. ORIGIN (Place an "X" in One Box Only)

☒ 1 Original Proceeding ☐ 2 Removed from State Court ☐ 3 Remanded from Appellate Court ☐ 4 Reinstated or Reopened ☐ 5 Transferred from another district (specify) ☐ 6 Multidistrict Litigation ☐ 7 Appeal to District Judge from Magistrate Judgment

VI. CAUSE OF ACTION
Cite the U.S. Civil Statute under which you are filing (Do not cite jurisdictional statutes unless diversity):
35 U.S.C. § 271
Brief description of cause: Patent Infringement

VII. REQUESTED IN COMPLAINT: ☐ CHECK IF THIS IS A CLASS ACTION UNDER F.R.C.P. 23 DEMAND $ CHECK YES only if demanded in complaint: JURY DEMAND: ☒ Yes ☐ No

VIII. RELATED CASE(S) IF ANY (See instructions): JUDGE _____ DOCKET NUMBER _____

DATE Feb. 12, 2008 SIGNATURE OF ATTORNEY OF RECORD

FOR OFFICE USE ONLY

RECEIPT # _____ AMOUNT _____ APPLYING IFP _____ JUDGE _____ MAG. JUDGE _____

JS 44 Reverse (Rev. 11/04)

INSTRUCTIONS FOR ATTORNEYS COMPLETING CIVIL COVER SHEET FORM JS 44

Authority For Civil Cover Sheet

The JS 44 civil cover sheet and the information contained herein neither replaces nor supplements the filings and service of pleading or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. Consequently, a civil cover sheet is submitted to the Clerk of Court for each civil complaint filed. The attorney filing a case should complete the form as follows:

I. **(a) Plaintiffs-Defendants.** Enter names (last, first, middle initial) of plaintiff and defendant. If the plaintiff or defendant is a government agency, use only the full name or standard abbreviations. If the plaintiff or defendant is an official within a government agency, identify first the agency and then the official, giving both name and title.

(b) County of Residence. For each civil case filed, except U.S. plaintiff cases, enter the name of the county where the first listed plaintiff resides at the time of filing. In U.S. plaintiff cases, enter the name of the county in which the first listed defendant resides at the time of filing. (NOTE: In land condemnation cases, the county of residence of the "defendant" is the location of the tract of land involved.)

(c) Attorneys. Enter the firm name, address, telephone number, and attorney of record. If there are several attorneys, list them on an attachment, noting in this section "(see attachment)".

II. **Jurisdiction.** The basis of jurisdiction is set forth under Rule 8(a), F.R.C.P., which requires that jurisdictions be shown in pleadings. Place an "X" in one of the boxes. If there is more than one basis of jurisdiction, precedence is given in the order shown below.

United States plaintiff. (1) Jurisdiction based on 28 U.S.C. 1345 and 1348. Suits by agencies and officers of the United States are included here.

United States defendant. (2) When the plaintiff is suing the United States, its officers or agencies, place an "X" in this box.

Federal question. (3) This refers to suits under 28 U.S.C. 1331, where jurisdiction arises under the Constitution of the United States, an amendment to the Constitution, an act of Congress or a treaty of the United States. In cases where the U.S. is a party, the U.S. plaintiff or defendant code takes precedence, and box 1 or 2 should be marked.

Diversity of citizenship. (4) This refers to suits under 28 U.S.C. 1332, where parties are citizens of different states. When Box 4 is checked, the citizenship of the different parties must be checked. (See Section III below; federal question actions take precedence over diversity cases.)

III. **Residence (citizenship) of Principal Parties.** This section of the JS 44 is to be completed if diversity of citizenship was indicated above. Mark this section for each principal party.

IV. **Nature of Suit.** Place an "X" in the appropriate box. If the nature of suit cannot be determined, be sure the cause of action, in Section VI below, is sufficient to enable the deputy clerk or the statistical clerks in the Administrative Office to determine the nature of suit. If the cause fits more than one nature of suit, select the most definitive.

V. **Origin.** Place an "X" in one of the seven boxes.

Original Proceedings. (1) Cases which originate in the United States district courts.

Removed from State Court. (2) Proceedings initiated in state courts may be removed to the district courts under Title 28 U.S.C., Section 1441. When the petition for removal is granted, check this box.

Remanded from Appellate Court. (3) Check this box for cases remanded to the district court for further action. Use the date of remand as the filing date.

Reinstated or Reopened. (4) Check this box for cases reinstated or reopened in the district court. Use the reopening date as the filing date.

Transferred from Another District. (5) For cases transferred under Title 28 U.S.C. Section 1404(a). Do not use this for within district transfers or multidistrict litigation transfers.

Multidistrict Litigation. (6) Check this box when a multidistrict case is transferred into the district under authority of Title 28 U.S.C. Section 1407. When this box is checked, do not check (5) above.

Appeal to District Judge from Magistrate Judgment. (7) Check this box for an appeal from a magistrate judge's decision.

VI. **Cause of Action.** Report the civil statute directly related to the cause of action and give a brief description of the cause. **Do not cite jurisdictional statutes unless diversity.** Example: U.S. Civil Statute: 47 USC 553
Brief Description: Unauthorized reception of cable service

VII. **Requested in Complaint.** Class Action. Place an "X" in this box if you are filing a class action under Rule 23, F.R.Cv.P.

Demand. In this space enter the dollar amount (in thousands of dollars) being demanded or indicate other demand such as a preliminary injunction.

Jury Demand. Check the appropriate box to indicate whether or not a jury is being demanded.

VIII. **Related Cases.** This section of the JS 44 is used to reference related pending cases if any. If there are related pending cases, insert the docket numbers and the corresponding judge names for such cases.

Date and Attorney Signature. Date and sign the civil cover sheet.

EXHIBIT 2

United States District Court, Central District of California

General Order

Category: Administrative

Order Number:	**Description:**	**Date Filed:**
98-03	**Method of Allocating Civil Cases Among the Divisions of the Central District Court of California**	**02/06/1998**

UNITED STATES DISTRICT COURT
FOR THE CENTRAL DISTRICT OF CALIFORNIA

In the Matter of	) **GENERAL ORDER NO. 98-03**
METHOD OF **ALLOCATING** CIVIL CASES AMONG THE DIVISIONS OF THE CENTRAL DISTRICT COURT OF CALIFORNIA	)

WHEREAS, in order to bring about an equal distribution of civil and criminal cases, the Court will periodically review and modify the method of **allocating** cases among the Divisions, and

WHEREAS, it now appears necessary to modify the civil case assignment rules to keep the caseload per judge in the Southern and Eastern Divisions in relative proximity to the caseloads of judges in the Western Division of the Court,

IT IS HEREBY ORDERED that General Order No. 349-A be amended as follows:

"1. Assignment of Civil Cases to the Southern Division

A. (i) Except as provided in paragraph (1) (B), a civil case shall be assigned to the Southern Division if one of the following three venue components as described below are within the Southern Division:

(a) the majority of all plaintiffs reside in the Southern Division or in a place outside the remainder of the Central District of California with an equal number deemed to be a Southern Division majority;

(b) the majority of all named defendants reside in the Southern Division or in a place outside the remainder of the Central District of California with an equal number deemed to be a Southern Division majority;

(c) the majority of all claims arose in the Southern Division or in a place outside the remainder of the Central District of California with an equal number deemed to be a Southern Division majority.

(ii) Except as provided in paragraph (1) (B), a civil case in which the United States or any agency thereof is a defendant, and in which the majority of all plaintiffs

reside in the Southern Division shall be assigned to the Southern Division. In addition, a civil case in which the United States or any agency thereof is a plaintiff, and in which the majority of all defendants reside in the Southern Division shall be assigned to the Southern Division.

(iii) With the exception of those cases assigned to the Western and Eastern Divisions pursuant to paragraph (1) (B) (iii) and section (2), all other civil cases shall be assigned to the Western Division.

B. (i) In order to balance the number of civil cases assigned to the judicial officers of the Western, Southern and Eastern Divisions, there shall be determined a maximum number of civil cases allowed for assignment to the Southern Division for a given period. This predetermined number shall be adjusted as needed.

(ii) Once the predetermined number of civil cases has been assigned to the Southern Division for the given period, all additional civil cases filed during that period shall be assigned to the Western Division.

(iii) If it appears that the actual number of civil cases assigned to the Southern Division for the given period will be substantially less than the predetermined number of cases allowed for assignment, the Clerk shall promptly notify the Chief Judge and Chair of the Case Management and Assignment Committee. To reduce the discrepancy, the Clerk may be directed to include in the Western or Eastern civil assignment wheels a specific number of civil cards for each Southern Division judicial officer for random assignment. The number of civil cards for Southern Division judicial officers added to the Western or Eastern Division assignment wheels shall be credited against the Southern Division predetermined number of cases allowed for assignment for the given period.

2. Assignment of Civil Cases to the Eastern Division

A. (i) Except as provided in paragraph (2) (B), a civil case shall be assigned to the Eastern Division if:

(a) each plaintiff resides in the Eastern Division or in a place outside the remainder of the Central District of California, and

(b) each named defendant resides in the Eastern Division or in a place outside the remainder of the Central District of California, and

(c) all claims arose in the Eastern Division or in a place outside the remainder of the Central District of California.

(ii) Except as provided in paragraph (2) (B), a civil case in which the United States or any agency thereof is a defendant, and in which all plaintiffs reside in Eastern Division shall be assigned to the Eastern Division. In addition, a civil case in which the United States or any agency thereof is a plaintiff, and in which all defendants reside in the Eastern Division shall be assigned to the Eastern Division.

(iii) With the exception of those cases assigned to the Western and Southern Divisions pursuant to paragraph (2) (B) (iii) and section (1), all other civil cases shall be assigned to the Western Division.

B. (i) In order to balance the number of civil cases assigned to the judicial

officers of the Western, Southern and Eastern Divisions, there shall be determined a maximum number of civil cases allowed for assignment to the Eastern Division for a given period. This predetermined number shall be adjusted as needed.

(ii) Once the predetermined number of civil cases has been assigned to the Eastern Division for the given period, all additional civil cases filed during that period shall be assigned to the Western Division.

(iii) If it appears that the actual number of civil cases assigned to the Eastern Division for the given period will be substantially less than the predetermined number of cases allowed for assignment, the Clerk shall promptly notify the Chief Judge and the Chair of the Case Management and Assignment Committee. To reduce the discrepancy, the Clerk may be directed to include in the Western or Southern civil assignment wheels a specific number of civil cards for each Eastern Division judicial officer for random assignment. The number of civil cards for Eastern Division judicial officers added to the Western or Southern Division assignment wheels shall be credited against the Eastern Division predetermined number of cases allowed for assignment for the given period.

These amendments shall be effective February 9, 1998.

United States District Court, Central District of California

General Order

Category: Administrative

Order Number:	Description:	Date Filed:
01-01	Method of Allocating Cases among the Divisions of the Central District Court of California	02/21/2001

UNITED STATES DISTRICT COURT
FOR THE CENTRAL DISTRICT OF CALIFORNIA

In the Matter of	
METHOD OF ALLOCATING CASES AMONG THE DIVISIONS OF THE CENTRAL DISTRICT COURT OF CALIFORNIA	**GENERAL ORDER NO. 01-01**
	(Amends General Orders No. 349, 349-A, 98-3 and 98-5)

IT IS HEREBY ORDERED that there shall be one district-wide Report and Recommendation Assignment Wheel which shall include all the active district judges and senior district judges whoso elect to be included. All cases referred to Magistrate Judges for a report and recommendation pursuant to General Order 194 and as outlined in the Local Rules Governing Duties of Magistrate Judges shall be randomly assigned through this one district-wide Report and Recommendation Assignment Wheel to the individual calendars of the district judges of this Court.

United States District Court, Central District of California

General Order

Category: Administrative

Order Number:	**Description:**	**Date Filed:**
02-06	**Method of Allocating Civil Cases in the Eastern Division of the Central District of California**	**03/01/2002**

UNITED STATES DISTRICT COURT
FOR THE CENTRAL DISTRICT OF CALIFORNIA

In the Matter of	) **GENERAL ORDER NO. 02-06**
METHOD OF **ALLOCATING** CIVIL CASES IN THE EASTERN DIVISION OF THE CENTRAL DISTRICT OF CALIFORNIA	)

WHEREAS, in order to bring about an equal distribution of civil and criminal cases, the Court will periodically review and modify the method of **allocating** cases among the Divisions, and

WHEREAS, it now appears necessary to modify the civil case assignment rules to keep the caseload per judge in the Eastern Division in relative proximity to the caseloads of judges in the Western and Southern Divisions of the Court,

IT IS HEREBY ORDERED that General Order 98-3 be amended as follows:

2. Assignment of Civil Cases to the Eastern Division

A. (i) Except as provided in paragraph (2) (B), a civil case shall be assigned to the Eastern Division if one of the following three venue components as described below are within the Eastern Division:

(a) the majority of all plaintiffs reside in the Eastern Division or in a place outside the remainder of the Central District of California with an equal number deemed to be an Eastern Division majority; (b) the majority of all named defendants reside in the Eastern Division or in a place outside the remainder of the Central District of California with an equal number deemed to be an Eastern Division majority;

(c) the majority of all claims arose in the Eastern Division or in a place outside the remainder of the Central District of California with an equal number deemed to be an Eastern Division majority.

This General Order shall take effect April 1, 2002.

EXHIBIT 3

United States

Edwards Lifesciences | Helping patients is our life's work, and life is now

HOME SPECIALTIES PROCEDURES PRODUCTS ABOUT US CAREERS INVESTOR RELATIONS CONTACT US SEARCH

Contact Us

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- Canada
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- Dominican Republic
- Europe
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Phone Numbers
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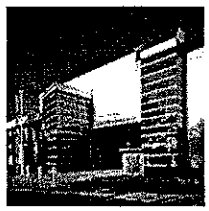
- Media
- Investor
- Technical Support

United States



United States
Global Headquarters
Edwards Lifesciences
One Edwards Way
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Phone: 949-250-2500
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(800-424-3278)
Driving Directions

Manufacturing
Irvine, California
Midvale, Utah

Print friendly version

EXHIBIT 4

FORM 10-K

EDWARDS LIFESCIENCES CORP - EW

Filed: February 29, 2008 (period: December 31, 2007)

Annual report which provides a comprehensive overview of the company for the past year

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the reimbursement levels for products. If a government were to decide to reduce reimbursement levels for Edwards Lifesciences' products, the Company's product pricing may be adversely affected.

Third party payors may deny reimbursement if they determine that a device used in a procedure was not used in accordance with cost-effective treatment methods as determined by such third party payors, or was used for an unapproved indication. Third party payors may also decline to reimburse for experimental procedures and devices. Edwards Lifesciences believes that many of its existing and future products are cost-effective, even though the one-time cost may be significant, because they are intended to reduce overall health care costs over a long period of time. Edwards Lifesciences cannot be certain whether these third party payors will recognize these cost savings or will merely focus on the lower initial costs associated with competing therapies. If Edwards Lifesciences' products are not considered cost-effective by third party payors, Edwards Lifesciences' customers may not be reimbursed for its products.

Edwards Lifesciences is also subject to various federal and state laws pertaining to healthcare pricing and fraud and abuse, including anti-kickback and false claims laws. Violations of these laws may be punishable by criminal or civil sanctions, including substantial fines, imprisonment and exclusion from participation in federal and state healthcare programs.

Item 1B. Unresolved Staff Comments

None.

Item 2. Properties

The locations and uses of the major properties of Edwards Lifesciences are as follows:

North America		
Irvine, California	(1)	Corporate Headquarters, Research and Development, Regulatory and Clinical Affairs, Manufacturing
Midvale, Utah	(1)	Administration, Research and Development, Manufacturing
Haina, The Dominican Republic	(2)	Manufacturing
Añasco, Puerto Rico	(2)	Manufacturing
Europe		
Saint Prex, Switzerland	(2)	Administration, Marketing
Horw, Switzerland	(2)	Manufacturing, Administration, Distribution
Asia		
Tokyo, Japan	(2)	Administration, Marketing, Distribution
Techview, Singapore	(2)	Manufacturing
Changi, Singapore	(2)	Manufacturing, Administration

(1) Owned property.

(2) Leased property.

The Dominican Republic lease expires in 2009; one of the Puerto Rico leases expires in 2008 and is expected to be renewed through 2018, and the other expires in 2016; the Horw, Switzerland lease is

renewed annually with appropriate termination notice provisions; the Saint Prex, Switzerland lease is renewed annually with a six month notification requirement; the Tokyo, Japan lease expires in 2009; the Techview, Singapore lease expires in 2008; and the Changi, Singapore landlease expires in 2036. The Company's properties have been well maintained, are in good operating condition and are adequate for current needs.

Item 3. Legal Proceedings

On August 18, 2003, Edwards Lifesciences filed a lawsuit against Medtronic, Inc. and its affiliate, Medtronic Vascular, Inc. (collectively, "Medtronic"), Cook, Inc. ("Cook") and W.L. Gore & Associates alleging infringement of a patent exclusively licensed to the Company. The lawsuit was filed in the United States District Court for the Northern District of California, seeking monetary damages and injunctive relief. On September 2, 2003, a second patent exclusively licensed to the Company was added to the lawsuit. As announced on January 23, 2006, Edwards Lifesciences settled this litigation with Medtronic. Edwards Lifesciences remains in litigation with Cook and W.L. Gore & Associates, each of which has answered and asserted various affirmative defenses and counterclaims.

On May 9, 2007, Edwards Lifesciences filed a lawsuit against CoreValve, Inc. ("CoreValve"), alleging that CoreValve's ReValving System infringes on a European patent, one of the Andersen family of patents. The lawsuit was filed in the District Patent Court in Dusseldorf, Germany, seeking injunctive and declaratory relief. On May 11, 2007, and June 20, 2007, CoreValve filed lawsuits in London, United Kingdom, and Munich, Germany, respectively, against the three inventors of this patent alleging that the patent is invalid. The Company then asserted that CoreValve's ReValving System infringes the Andersen patent in the United Kingdom. Edwards Lifesciences recently purchased the Andersen patent family and now has the exclusive right, as owner instead of licensee, to enforce the patents and to conduct the defense in the invalidity proceedings. On February 12, 2008, the Company filed a lawsuit against CoreValve in the United States alleging infringement of three of the Andersen patents.

On February 1, 2008, Cook filed a lawsuit in the District Patent Court in Dusseldorf, Germany against Edwards Lifesciences alleging that the*Edwards SAPIEN* transcatheter heart valve infringes on a Cook patent. The Company will vigorously defend the lawsuit.

In addition, Edwards Lifesciences is or may be a party to, or may be otherwise responsible for, pending or threatened lawsuits related primarily to products and services currently or formerly manufactured or performed, as applicable, by Edwards Lifesciences. Such cases and claims raise difficult and complex factual and legal issues and are subject to many uncertainties and complexities, including, but not limited to, the facts and circumstances of each particular case or claim, the jurisdiction in which each suit is brought, and differences in applicable law. Upon resolution of any such legal matters or other claims, Edwards Lifesciences may incur charges in excess of established reserves. While any such charge could have a material adverse impact on Edwards Lifesciences' net income or net cash flows in the period in which it is recorded or paid, management does not believe that any such charge relating to any currently pending lawsuit would have a material adverse effect on Edwards Lifesciences' financial position, results of operations or liquidity.

Edwards Lifesciences is also subject to various environmental laws and regulations both within and outside of the United States. The operations of Edwards Lifesciences, like those of other medical device companies, involve the use of substances regulated under environmental laws, primarily in manufacturing

EXHIBIT 5

(1) The Texarkana Division comprises the counties of Hempstead, Howard, Lafayette, Little River, Miller, Nevada, and Sevier.

Court for the Texarkana Division shall be held at Texarkana, and may be held anywhere within the Federal courthouse in Texarkana that is located astride the State line between Texas and Arkansas.

(2) The El Dorado Division comprises the counties of Ashley, Bradley, Calhoun, Columbia, Ouachita, and Union.

Court for the El Dorado Division shall be held at El Dorado.

(3) The Fort Smith Division comprises the counties of Crawford, Franklin, Johnson, Logan, Polk, Scott, and Sebastian.

Court for the Fort Smith Division shall be held at Fort Smith.

(4) The Harrison Division comprises the counties of Baxter, Boone, Carroll, Marion, Newton, and Searcy.

Court for the Harrison Division shall be held at Harrison.

(5) The Fayetteville Division comprises the counties of Benton, Madison, and Washington.

Court for the Fayetteville Division shall be held at Fayetteville.

(6) The Hot Springs Division comprises the counties of Clark, Garland, Hot Springs, Montgomery, and Pike.

Court for the Hot Springs Division shall be held at Hot Springs.

(June 25, 1948, ch. 646, 62 Stat. 874; Pub. L. 87–36, §5, May 19, 1961, 75 Stat. 84; Pub. L. 108–455, §3, Dec. 10, 2004, 118 Stat. 3628.)

HISTORICAL AND REVISION NOTES

Based on title 28, U.S.C., 1940 ed., §144 (Mar. 3, 1911, ch. 231, §71, 36 Stat. 1106; Apr. 12, 1924, ch. 87, §1, 43 Stat. 90; Feb. 17, 1925, ch. 252, 43 Stat. 948; Apr. 16, 1926, ch. 147, §1, 44 Stat. 296; Apr. 21, 1926, ch. 168, 44 Stat. 304; Feb. 7, 1928, ch. 29, §1, 45 Stat. 58; Apr. 17, 1940, ch. 100, 54 Stat. 109; June 11, 1940, ch. 321, §1, 54 Stat. 302).

A provision making inoperative the terms of the last paragraph of this section, whenever court accommodations shall be provided in Federal buildings was omitted as unnecessary. When such buildings become available the Director of the Administrative Office of the United States Courts will, under section 604 of this title, provide court accommodations therein.

Provisions relating to places for maintenance of clerks' offices and requiring said offices to be kept open at all times were omitted as covered by sections 452 and 751 of this title.

The provision authorizing the referee in bankruptcy for the western division of the eastern district to serve by appointment in the Hot Springs division of the western district is to be transferred to title 11, U.S.C., 1940 ed., Bankruptcy.

The provision with reference to court accommodations at Fayetteville and Hot Springs was omitted as covered by section 142 of this title.

Changes in arrangement and phraseology were made.

AMENDMENTS

2004—Subsec. (b)(1). Pub. L. 108–455 inserted ", and may be held anywhere within the Federal courthouse in Texarkana that is located astride the State line between Texas and Arkansas" after "held at Texarkana".

1961—Subsec. (a). Pub. L. 87–36 struck out from enumeration in par. (1) the parish of Desha and in par. (2) the parishes of Arkansas, Chicot, Cleveland, Dallas, Drew, Grant, Jefferson, and Lincoln, added par. (3) consisting of such parishes, and redesignated former par. (3) and (4) as (4) and (5), respectively.

§ 84. California

California is divided into four judicial districts to be known as the Northern, Eastern, Central, and Southern Districts of California.

Northern District

(a) The Northern District comprises the counties of Alameda, Contra Costa, Del Norte, Humboldt, Lake, Marin, Mendocino, Monterey, Napa, San Benito, Santa Clara, Santa Cruz, San Francisco, San Mateo, and Sonoma.

Court for the Northern District shall be held at Eureka, Oakland, San Francisco, and San Jose.

Eastern District

(b) The Eastern District comprises the counties of Alpine, Amador, Butte, Calaveras, Colusa, El Dorado, Fresno, Glenn, Inyo, Kern, Kings, Lassen, Madera, Mariposa, Merced, Modoc, Mono, Nevada, Placer, Plumas, Sacramento, San Joaquin, Shasta, Sierra, Siskiyou, Solano, Stanislaus, Sutter, Tehama, Trinity, Tulare, Tuolumne, Yolo, and Yuba.

Court for the Eastern District shall be held at Fresno, Redding, and Sacramento.

Central District

(c) The Central District comprises 3 divisions.

(1) The Eastern Division comprises the counties of Riverside and San Bernardino.

Court for the Eastern Division shall be held at a suitable site in the city of Riverside, the city of San Bernardino, or not more than 5 miles from the boundary of either such city.

(2) The Western Division comprises the counties of Los Angeles, San Luis Obispo, Santa Barbara, and Ventura.

Court for the Western Division shall be held at Los Angeles.

(3) The Southern Division comprises Orange County.

Court for the Southern Division shall be held at Santa Ana.

Southern District

(d) The Southern District comprises the counties of Imperial and San Diego.

Court for the Southern District shall be held at San Diego.

(June 25, 1948, ch. 646, 62 Stat. 875; Pub. L. 89–372, §3(a), Mar. 18, 1966, 80 Stat. 75; Pub. L. 96–462, §2, Oct. 15, 1980, 94 Stat. 2053; Pub. L. 102–357, §2, Aug. 26, 1992, 106 Stat. 958.)

HISTORICAL AND REVISION NOTES

Based on title 28, U.S.C., 1940 ed., §145 and section 76 of title 16, Conservation (Mar. 3, 1911, ch. 231, §72, 36 Stat. 1107; May 16, 1916, ch. 122, 39 Stat. 122; June 2, 1920, ch. 218, §2, 41 Stat. 731; Mar. 1, 1929, ch. 421, 45 Stat. 1424).

A provision relating to the place for maintenance of a clerk's office, and requiring such office to be kept open at all times, was omitted as covered by sections 452 and 751 of this title.

Exhibit 5
Page 1

Changes in arrangement and phraseology were made.

AMENDMENTS

1992—Subsec. (c). Pub. L. 102–357 amended subsec. (c) generally. Prior to amendment, subsec. (c) read as follows: "The Central District comprises the counties of Los Angeles, Orange, Riverside, San Bernardino, San Luis Obispo, Santa Barbara, and Ventura.

"Court for the Central District shall be held at Los Angeles and Santa Ana."

1980—Subsec. (c). Pub. L. 96–462 inserted "and Santa Ana" after "at Los Angeles".

1966—Pub. L. 89–372 expanded the number of judicial districts in California from two to four by creating an Eastern and a Central District in addition to the existing Northern and Southern Districts, removed the provisions separating the Northern and Southern Districts into divisions, transferred to the newly created Eastern Division the counties of Alpine, Almador, Butte, Calaveras, Colusa, El Dorado, Glenn, Lassen, Modoc, Mono, Nevada, Placer, Plumas, Sacramento, San Joaquin, Shasta, Sierra, Siskiyou, Solano, Stanislaus, Sutter, Tehama, Trinity, Tuolumne, Yolo, and Yuba from the Northern District and Fresno, Inyo Kern, Kings, Madera, Mariposa, Merced, and Tulare from the Southern District, transferred to the newly created Central District the counties of Los Angeles, Orange, Riverside, San Bernardino, San Louis Obispo, Santa Barbara, and Ventura from the Southern District, substituted Eureka, Oakland, San Francisco, and San Jose for Eureka, Sacramento, and San Francisco as places for holding court for the Northern District, removed Fresno and Los Angeles from the list of places for holding court for the Southern District leaving San Diego as the only place for holding of court in the Southern District, and provided for the holding of court in Los Angeles for the Central District and in Fresno, Redding, and Sacramento for the Eastern District.

EFFECTIVE DATE OF 1992 AMENDMENT

Section 3 of Pub. L. 102–357 provided that:

"(a) IN GENERAL.—This Act [amending this section and enacting provisions set out below] and the amendments made by this Act shall take effect 6 months after the date of the enactment of this Act [Aug. 26, 1992].

"(b) PENDING CASES NOT AFFECTED.—This Act and the amendments made by this Act shall not affect any action commenced before the effective date of this Act and pending in the United States District Court for the Central District of California on such date.

"(c) JURIES NOT AFFECTED.—This Act and the amendments made by this Act shall not affect the composition, or preclude the service, of any grand or petit jury summoned, empaneled, or actually serving in the Central Judicial District of California on the effective date of this Act."

EFFECTIVE DATE OF 1980 AMENDMENT; SAVINGS PROVISION

Section 7 of Pub. L. 96–462 provided that:

"(a) This Act and the amendments made by this Act [amending this section and sections 95, 105, 113, and 124 of this title and enacting provisions set out as notes under this section and sections 95, 105, and 113 of this title] shall take effect on October 1, 1981.

"(b) Nothing in this Act shall affect the composition or preclude the service of any grand or petit juror summoned, empaneled, or actually serving in any judicial district on the effective date of this Act [Oct. 1, 1981]."

EFFECTIVE DATE OF 1966 AMENDMENT

Section 3(1) of Pub. L. 89–372 provided that: "The provisions of this section [amending this section and enacting provisions set out as a note under this section and section 133 of this title] shall become effective six months after the date of enactment of this Act [Mar. 18, 1966]."

CONGRESSIONAL FINDINGS CONCERNING CREATION OF THREE DIVISIONS IN CENTRAL DISTRICT

Section 1 of Pub. L. 102–357 provided that: "The Congress makes the following findings:

"(1) The Federal Government has the responsibility to provide quality services which are readily accessible to the people it serves.

"(2) The court facilities in the Central Judicial District of California are presently inadequate, and current and projected growth exacerbates the problem.

"(3) The population demographics of southern California have changed dramatically over the last decade, as the center of population shifts inland. Between 1980 and 1990, the population of Riverside County increased 76.5 percent, and San Bernardino County's population increased 58.5 percent, to a combined population of 2,600,000.

"(4) In the next 15 years, the population in Riverside and San Bernardino Counties is expected to increase again by 70 percent, and 67 percent, respectively. By the year 2005, Riverside and San Bernardino Counties will have 4,400,000 residents.

"(5) As a result of the population growth, the freeways connecting the Pacific coast and the inland areas are tremendously overburdened, and Federal offices along the coast are no longer accessible to the residents of Riverside and San Bernardino Counties.

"(6) The creation of 3 divisions in the Central Judicial District of California is urgently needed to provide for the delivery of judicial services to all areas and all residents of the Central Judicial District of California."

STUDY OF JUDICIAL BUSINESS IN CENTRAL DISTRICT, CALIFORNIA AND EASTERN DISTRICT, NEW YORK AND RECOMMENDATIONS FOR CREATION OF NEW JUDICIAL DISTRICTS

Pub. L. 95–573, § 5, Nov. 2, 1978, 92 Stat. 2458, required the Director of the Administrative Office of the United States Courts to conduct a study of the judicial business of the Central District of California and the Eastern District of New York, within one year of Nov. 2, 1978, and to make recommendations to Congress with respect to the need for creation of new judicial districts.

CREATION OF EASTERN AND CENTRAL DISTRICTS: TRANSFER OF DISTRICT JUDGES; TRANSFER AND APPOINTMENT OF UNITED STATES ATTORNEYS AND UNITED STATES MARSHALS

Section 3(b)–(g) of Pub. L. 89–372 provided that:

"(b) The two district judges for the northern district of California holding office on the day before the effective date of this section [see Effective Date of 1966 Amendment note above] and whose official station is Sacramento shall, on and after such date, be district judges for the eastern district of California. All other district judges for the northern district of California holding office on the day before the effective date of this section shall, on and after such date, be district judges for the northern district of California.

"(c) The district judge for the southern district of California, residing in the northern division thereof and holding office on the day before the effective date of this section [see Effective Date of 1966 Amendment note above], shall, on and after such date, be a district judge for the eastern district of California. The two district judges for the southern district of California holding office on the day before the effective date of this section [see Effective Date of 1966 Amendment note above], and whose official station is San Diego shall, on and after such date, be the district judges for the southern district of California. All other district judges for the southern district of California holding office on the day before the effective date of this section shall, on and after such date, be district judges for the central district of California.

"(d) Nothing in this Act [amending this section and sections 44 and 133 of this title and enacting provisions

set out as notes under this section and sections 44 and 133 of this title] shall in any manner affect the tenure of office of the United States attorney and the United States marshal for the northern district of California who are in office on the effective date of this section [see Effective Date of 1966 Amendment note above], and who shall be during the remainder of their present terms of office the United States attorney and marshal for such district as constituted by this Act.

"(e) Nothing in this Act [amending this section and sections 44 and 133 of this title and enacting provisions set out as notes under this section and sections 44 and 133 of this title] shall in any manner affect the tenure of office of the United States attorney and the United States marshal for the southern district of California who are in office on the effective date of this section, and who shall be during the remainder of their present terms of office the United States attorney and marshal for the central district of California.

"(f) The President shall appoint, by and with the advice and consent of the Senate, a United States attorney and a United States marshal for the southern district of California.

"(g) The President shall appoint, by and with the advice and consent of the Senate, a United States attorney and a United States marshal for the eastern district of California."

§ 85. Colorado

Colorado constitutes one judicial district.
Court shall be held at Boulder, Colorado Springs, Denver, Durango, Grand Junction, Montrose, Pueblo, and Sterling.

(June 25, 1948, ch. 646, 62 Stat. 875; Pub. L. 98–620, title IV, §409, Nov. 8, 1984, 98 Stat. 3362; Pub. L. 108–455, §5, Dec. 10, 2004, 118 Stat. 3629; Pub. L. 108–482, title III, §301, Dec. 23, 2004, 118 Stat. 3918.)

HISTORICAL AND REVISION NOTES

Based on title 28, U.S.C., 1940 ed., §146 (Mar. 3, 1911, ch. 231, §73, 36 Stat. 1103; June 12, 1916, ch. 143, 39 Stat. 225; May 29, 1924, ch. 209, 43 Stat. 243).

A provision for furnishing rooms and accommodations at Sterling was omitted as obsolete upon advice from the Director of the Administrative Office of the United States Courts that Federal accommodations are now available.

A provision authorizing adjournment at Denver when there is not business for terms at other places, is incorporated in section 138 of this title.

Provisions as to clerk's and marshal's deputies and maintenance of offices were deleted as covered by sections 541 [see 561], 542 [see 561], and 751 of this title.

Changes in arrangement and phraseology were made.

AMENDMENTS

2004—Pub. L. 108–455 and 108–482 amended section identically, inserting "Colorado Springs," after "Boulder,".

1984—Pub. L. 98–620 provided for holding court at Boulder.

EFFECTIVE DATE OF 1984 AMENDMENT

Section 411 of Pub. L. 98–620 provided that:

"(a) The amendments made by this subtitle [subtitle B (§§404–411) of title IV of Pub. L. 98–620, amending this section and sections 90, 93, 112, 124, and 126 of this title and enacting provisions set out as notes under sections 1, 90, 93, and 124 of this title] shall take effect on January 1, 1985.

"(b) The amendments made by this subtitle shall not affect the composition, or preclude the service, of any grand or petit jury summoned, impaneled, or actually serving on the effective date of this subtitle [Jan. 1, 1985]."

§ 86. Connecticut

Connecticut constitutes one judicial district.
Court shall be held at Bridgeport, Hartford, New Haven, New London, and Waterbury.

(June 25, 1948, ch. 646, 62 Stat. 875; Pub. L. 87–36, §3(b), May 19, 1961, 75 Stat. 83; Pub. L. 89–558, Sept. 7, 1966, 80 Stat. 705.)

HISTORICAL AND REVISION NOTES

Based on title 28, U.S.C., 1940 ed., §147 (Mar. 3, 1911, ch. 231, §74, 36 Stat. 1108; Feb. 27, 1921, ch. 74, 41 Stat. 1146; June 15, 1933, ch. 80, 48 Stat. 148; Dec. 28, 1945, ch. 599, 59 Stat. 663).

Changes in arrangement and phraseology were made.

AMENDMENTS

1966—Pub. L. 89–558 provided for holding court at New London.

1961—Pub. L. 87–36 provided for holding court at Bridgeport and Waterbury.

§ 87. Delaware

Delaware constitutes one judicial district.
Court shall be held at Wilmington.

(June 25, 1948, ch. 646, 62 Stat. 875.)

HISTORICAL AND REVISION NOTES

Based on title 28, U.S.C., 1940 ed., §148 (Mar. 3, 1911, ch. 231, §75, 36 Stat. 1108).

Minor changes in phraseology were made.

§ 88. District of Columbia

The District of Columbia constitutes one judicial district.
Court shall be held at Washington.

(June 25, 1948, ch. 646, 62 Stat. 875.)

HISTORICAL AND REVISION NOTES

This section expressly makes the District of Columbia a judicial district of the United States.

Section 41 of this title also makes the District of Columbia a judicial circuit of the United States.

Section 11–305 of the District of Columbia Code, 1940 ed., provides that the District Court of the United States for the District of Columbia shall possess the same powers and exercise the same jurisdiction as the district courts of the United States, and shall be deemed a court of the United States.

It is consonant with the ruling of the Supreme Court in *O'Donoghue v. United States*, 1933, 53 S.Ct. 740, 289 U.S. 516, 77 L.Ed. 1356, that the (then called) Supreme Court and Court of Appeals of the District of Columbia are constitutional courts of the United States, ordained and established under article III of the Constitution, Congress enacted that the Court of Appeals "shall hereafter be known as the United States Court of Appeals for the District of Columbia" (Act of June 7, 1934, 48 Stat. 926); and also changed the name of the Supreme Court of the District of Columbia to "district court of the United States for the District of Columbia" (Act of June 25, 1936, 49 Stat. 1921). In *Federal Trade Commission v. Klesner*, 1927, 47 S.Ct. 557, 274 U.S. 145, 71 L.Ed. 972, the Supreme Court ruled: "* * * The parallelism between the Supreme Court of the District [of Columbia] and the Court of Appeals of the District [of Columbia], on the one hand, and the district courts of the United States and the circuit courts of appeals, on the other, in the consideration and disposition of cases involving what among the States would be regarded as within Federal jurisdiction, is complete." See also to the same effect *Clairborne-Annapolis Ferry Company v. United States*, 1932, 52 S.Ct. 440, 285 U.S. 382, 76 L.Ed. 808.

§ 89. Florida

Florida is divided into three judicial districts to be known as the Northern, Middle, and Southern Districts of Florida.

EXHIBIT 6

U.S. DISTRICT COURT - JUDICIAL CASELOAD PROFILE

			12-MONTH PERIOD ENDING SEPTEMBER 30							
DELAWARE			2007	2006	2005	2004	2003	2002	Numerical Standing	
OVERALL CASELOAD STATISTICS	Filings*		1,065	1,077	1,190	1,797	1,362	2,028	U.S.	Circuit
	Terminations		975	1,419	1,448	1,516	1,507	1,478		
	Pending		1,511	1,501	1,853	2,085	1,836	1,999		
	% Change in Total Filings	Over Last Year		-1.1					50	4
		Over Earlier Years			-10.5	-40.7	-21.8	-47.5	90	6
Number of Judgeships			4	4	4	4	4	4		
Vacant Judgeship Months**			9.5	.0	.0	.0	1.9	3.1		
ACTIONS PER JUDGESHIP	FILINGS	Total	267	270	298	449	340	507	80	5
		Civil	218	233	264	414	306	462	72	5
		Criminal Felony	38	30	28	29	25	38	81	5
		Supervised Release Hearings**	11	7	6	6	9	7	82	3
	Pending Cases		378	375	463	521	459	500	42	5
	Weighted Filings**		379	367	422	534	424	516	61	3
	Terminations		244	355	362	379	377	370	83	5
	Trials Completed		21	15	20	19	23	18	43	3
MEDIAN TIMES (months)	From Filing to Disposition	Criminal Felony	8.5	9.3	9.4	9.1	8.3	9.8	43	2
		Civil**	12.5	16.8	10.9	14.0	11.2	8.2	88	5
	From Filing to Trial** (Civil Only)		27.0	26.0	23.5	26.0	24.0	22.5	54	3
OTHER	Civil Cases Over 3 Years Old**	Number	108	142	156	65	66	99		
		Percentage	8.2	10.6	9.1	3.4	3.9	5.4	77	5
	Average Number of Felony Defendants Filed Per Case		1.1	1.2	1.2	1.2	1.3	1.1		
	Jurors	Avg. Present for Jury Selection	41.56	39.60	39.82	38.50	34.98	33.84		
		Percent Not Selected or Challenged	31.7	24.1	22.8	20.9	24.0	24.4		

2007 CIVIL AND CRIMINAL FELONY FILINGS BY NATURE OF SUIT AND OFFENSE

Type of	TOTAL	A	B	C	D	E	F	G	H	I	J	K	L
Civil	870	28	4	229	9	3	32	68	39	176	103	14	165
Criminal*	150	1	26	25	46	20	2	17	5	2	-	1	5

* Filings in the "Overall Caseload Statistics" section include criminal transfers, while filings "By Nature of Offense" do not.
** See "Explanation of Selected Terms."
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U.S. DISTRICT COURT - JUDICIAL CASELOAD PROFILE

			12-MONTH PERIOD ENDING SEPTEMBER 30							
CALIFORNIA CENTRAL			2007	2006	2005	2004	2003	2002	Numerical Standing	
OVERALL CASELOAD STATISTICS	Filings*		14,154	12,909	14,630	16,938	14,720	15,440	U.S.	Circuit
	Terminations		13,642	13,680	16,173	15,269	15,800	16,936		
	Pending		11,817	12,401	13,180	14,720	13,129	14,525		
	% Change in Total Filings	Over Last Year		9.6					11	3
		Over Earlier Years			-3.3	-16.4	-3.9	-8.3	51	8
Number of Judgeships			28	28	28	28	28	27		
Vacant Judgeship Months**			31.2	53.9	24.8	2.3	23.6	63.9		
ACTIONS PER JUDGESHIP	FILINGS	Total	505	461	523	605	526	572	24	7
		Civil	425	397	450	515	451	490	12	3
		Criminal Felony	47	36	45	60	49	58	73	11
		Supervised Release Hearings**	33	28	28	30	26	24	26	9
	Pending Cases		422	443	471	526	469	538	28	6
	Weighted Filings**		551	518	565	651	590	584	15	5
	Terminations		487	489	578	545	564	627	29	6
	Trials Completed		12	12	13	12	14	12	79	11
MEDIAN TIMES (months)	From Filing to Disposition	Criminal Felony	12.1	12.4	10.3	8.2	9.4	8.6	81	13
		Civil**	6.8	7.2	7.4	7.3	7.5	7.9	12	3
	From Filing to Trial** (Civil Only)		21.3	21.3	20.5	17.8	21.2	20.0	29	4
OTHER	Civil Cases Over 3 Years Old**	Number	712	1,240	809	624	609	650		
		Percentage	7.2	11.6	7.2	5.0	5.4	5.2	72	12
	Average Number of Felony Defendants Filed Per Case		1.3	1.6	1.5	1.4	1.4	1.4		
	Jurors	Avg. Present for Jury Selection	60.57	64.08	47.33	49.01	49.49	54.63		
		Percent Not Selected or Challenged	56.5	55.7	48.3	49.4	51.6	55.5		

2007 CIVIL AND CRIMINAL FELONY FILINGS BY NATURE OF SUIT AND OFFENSE

Type of	TOTAL	A	B	C	D	E	F	G	H	I	J	K	L
Civil	11904	1005	205	2735	263	52	927	1325	545	1566	1241	51	1989
Criminal*	1314	5	95	553	79	285	44	73	35	54	10	34	47

* Filings in the "Overall Caseload Statistics" section include criminal transfers, while filings "By Nature of Offense" do not.
** See "Explanation of Selected Terms."
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